



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Examiner : Deborah K. Ware
Group Art Unit: : 1651
Applicants : Wong et al.
Serial No. : 09/912,494
Filed : July 24, 2001
For : ULTRAPURE PROTEIN MATERIAL

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Hon. Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

APPLICANT'S BRIEF ON APPEAL

Richard B. Taylor
Registration No. 37,248
P.O. Box 88940
St. Louis, MO 63188

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TABLE OF CASES CITED (IN ORDER CITED)
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Trintec Industries Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597 (CAFC 2002);
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REAL PARTY IN INTEREST

Solae, LLC (formerly Protein Technologies International, Inc.), a corporation of the State of Delaware located at 1034 Danforth Dr., St Louis, MO 63102, is the real party in interest in the appeal of the present application, having been assigned the application by the inventors.

RELATED APPEALS AND INTERFERENCES

An appeal is pending for patent application U.S. Serial No. 09/785,936, which is related to the present patent application. Both the present patent application and U.S. Ser. No. 09/785,936 claim priority from patent application U.S. Serial No. 08/996,976 filed December 23, 1997 (now abandoned), where the present application is a continuation-in-part application of U.S. Ser. No. 08/996,976, and U.S. Ser. No. 09/785,936 is a divisional application of U.S. Ser. No. 08/996,976. The present application is directed to claims for a composition of matter, whereas U.S. Ser. No. 09/785,936 is directed to claims for a process.

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STATUS OF CLAIMS

Claims 1-36 and 92-105 were originally filed in the present application. An attempt to cancel claims 1-36 and claims 92-102 and to add claims 106-110 was made in a preliminary amendment. The preliminary amendment was not entered with respect to the claims, as the Examiner indicated that only claims 1-78 should have been pending in the application. The Examiner required an election between claims 1-36 or claims 37-78. Applicants elected claims 1-36 with traverse while indicating that the desired claims were claims 103-110 (not entered) which Applicants believed were properly entered by the preliminary amendment. In an office action dated January 27, 2003 the Examiner maintained that claims 103-110 were properly not entered into the application, and claims 1-36 were rejected, in part because they were the same claims pending in the co-currently appealed application Ser. No. 09/785,936. In a response dated April 10, 2003, Applicants canceled claims 1-36 and added the desired claims as claims 79-86 (the previously non-entered claims 103-110). Claims 79-86 were finally rejected in an office action dated July 1, 2003. Applicants filed a response after final rejection on August 7, 2003 regarding claims 79-86 in which claims 83-86 were amended in order to place the claims in better condition for appeal. The final rejection of claims 79-86 was maintained in an advisory action dated October 14, 2003. Claims 79-86 remain pending in the present application and are the subject of this appeal. A copy of the pending appealed claims is attached in Appendix A. No claims are allowed.

STATUS OF AMENDMENTS

An amendment after final rejection was filed on August 7, 2003 to amend claims 83-86. The amendment after final rejection was filed to overcome certain of the Examiner's objections and place the claims in better condition for this appeal. The amendment has been entered in the file of the present application.

SUMMARY OF THE INVENTION

The present invention provides a composition that is a soy protein material containing at most 4000 mg/kg of ribonucleic acids and that is substantially devoid of

ribonuclease enzymes. Soy protein materials containing low levels of ribonucleic acids are important nutritionally, particularly if the soy protein material is to be used as a protein source in an infant formula. Ribonucleic acids are present in soy protein materials in higher concentrations than in human milk. In order to produce a human milk-like infant formula that utilizes a soy protein material, it is desirable to reduce the concentration of ribonucleic acids in the soy protein material below the normal concentration of ribonucleic acids in human milk, and add the proper amount of ribonucleic acids back to the formulation to approximate the concentration of ribonucleic acids in human milk. Soy protein isolates are utilized as the source of soy protein in soy protein infant formulas. Soy protein isolates typically have a ribonucleic acid content in the range of 16,000 mg/kg to 23,000 mg/kg. Prior to the present invention, ribonucleic acid content could be reduced in a soy protein material by degrading the ribonucleic acids with a ribonuclease enzyme. Use of ribonuclease enzymes, however, is not a commercially feasible method of reducing ribonucleic acid concentrations in soy protein isolates for use in infant formulas since ribonuclease enzymes are prohibitively expensive.

The present invention provides a soy protein material composition containing low amounts of ribonucleic acids, wherein the ribonucleic acids are degraded with an acid phosphatase enzyme so the soy protein material contains no ribonuclease enzymes.

Claim 79, the only independent claim in the present application is directed to:

A composition comprising, a soy protein material containing at most 4000 mg/kg ribonucleic acids and being substantially devoid of ribonuclease enzymes.

Acid phosphatase enzymes are significantly less expensive than ribonuclease enzymes, therefore, the soy protein material composition containing low amounts of ribonucleic acids can be made on a commercially practical scale.

ISSUES

1. Whether, under 35 U.S.C. §102(b), the subject matter of claims 79-86 is anticipated by the disclosure of EP 0 380 343.
2. Whether, under 35 U.S.C. §103(a), the subject matter of claims 79-86 is obvious over the disclosure of EP 0 380 343.

3. Whether, under 35 U.S.C. §103(a), the subject matter of claims 79 and 86 are obvious over EP 0 380 343 in view of U.S. Patent No. 6,313,328 to Ulrich et al.
4. Whether, under 35 U.S.C. §102(e), the subject matter of claims 79-86 is anticipated by U.S. Patent No. 6,313,273 to Thomas et al.
5. Whether, under 35 U.S.C. §103(a), the subject matter of claims 79-86 is obvious over U.S. Patent No. 6,313,273 to Thomas et al.
6. Whether, under 35 U.S.C. §103(a), the subject matter of claims 79 and 86 is obvious over U.S. Patent No. 6,313,273 to Thomas et al. in view of U.S. Patent No. 6,313,328 to Ulrich et al.

GROUPING OF CLAIMS

Claims 79-86 as one group.

ARGUMENT

The §102(b) and §103(a) rejection of claims 79-86 over EP 0 380 343

EP 0 380 343 A2

EP 0 380 343 A2 (the “EP ‘343 patent”, attached as Appendix B) teaches a method for production of phytate-free or low-phytate soy protein isolates or soy protein concentrates. The EP ‘343 patent is directed to a method of degrading phytates with one or more phytate-degrading enzymes. As set forth in on page 6, lines 38-41 of the ‘343 patent:

“Stated most simply, in its broadest terms the present invention comprises:

- (a) suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation comprising one or more phytate-degrading enzymes; and
- (b) isolating the resulting phytate-free or low phytate soy protein.”

Eight aspects of the EP ‘343 invention are provided on pages 4 and 5 in which phytates are eliminated or reduced in a soy protein containing composition by treating the soy protein containing composition with either 1) at least one phytate degrading enzyme; or 2) a phytase reducing amount of FINASE S. The phytate-degrading enzymes useful for degrading phytates and phytic acids in the method of the EP ‘343 patent include phytase

and acid phosphatases (page 6, line 19). A preferred enzyme preparation is the FINASE[®] enzyme preparation (page 6, lines 26-28). FINASE[®] is disclosed as an enzyme preparation containing one or more phytate-degrading enzymes (page 7, lines 7-10). There is no mention in the EP '343 patent of ribonucleic acids at all, and no mention of the concentration of ribonucleic acids in a soy protein material.

The §102(b) rejection

Claims 79-86 stand rejected as anticipated under 35 U.S.C. §102(b) by the disclosure of EP 0 380 343. To constitute anticipation, all material elements of a claim must be found in one prior art source. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1967).

As set forth above, claim 79 is the only independent claim, and provides a composition comprising a soy protein material containing at most 4000 mg/kg ribonucleic acids ("RNAs") and being substantially devoid of ribonuclease enzymes.

In the Office Action of July 1, 2003, the claims were finally rejected as being anticipated by the EP '343 patent disclosure because allegedly "the claims are identical to the disclosure of the EP reference"—and allegedly the specific ranges of RNAs claimed (<4000 mg/kg, <2000 mg/kg, <1500 mg/kg) as well as the specific ranges of phytic acids disclosed in the dependent claims (<0.45%, <0.2%, and <0.1%) are clearly ranges that fall within the ranges disclosed by the reference. Although EP '343 reference contains no disclosure of any ranges of RNA in a soy protein material, the claims were rejected on the basis that the (claimed) low amounts of RNAs in the soy protein material are inherent to the cited disclosure because the claimed RNA ranges are inherent in the soy protein isolate of the reference.

In their response after final of August 7, 2003, Applicants stated that claims 79-86 are neither explicitly nor inherently anticipated by the EP '343 reference. Applicants stated that the claims are not explicitly anticipated by the reference since the claims include the limitation that a soy protein material contain 4000 mg/kg of RNA at most, and the reference makes no mention of RNA at all. Applicants further averred that the claims are not inherently anticipated because the claimed concentrations of RNA in a soy protein material are not a necessary consequence of practicing the process of the EP '343 reference in accordance with the intent of the EP '343 reference. Specifically, the

Applicants noted that the EP '343 reference clearly states the intent of the process of the reference is to produce a phytate-free or low phytate soy protein by suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation containing one or more phytate-degrading enzymes (*see* page 6, lines 38-41 of the '343 reference, quoted above), and that the result of practicing the process as disclosed in the EP '343 patent did not necessarily result in a soy protein material containing the claimed levels of RNA. Applicants averred that practice of the process of the EP '343 patent did not necessarily result in the claimed levels of RNA for two reasons: 1) the phytate-degrading enzymes disclosed by the EP '343 reference included non-acid phosphatase phytases that did not degrade RNA at all, so the claimed levels of RNA were not necessarily attained merely by contacting a phytate degrading enzyme with a soy protein material; and 2) even if the phytate-degrading enzymes of the reference were limited to acid phosphatase enzymes, the conditions disclosed in the EP '343 reference could produce a soy protein material containing reduced levels of RNA relative to an untreated similar soy protein material, but the levels of RNA could be above the claimed levels of RNA. The Applicants provided experimental proof that the phytate levels of a soy protein material could be reduced with a phytate degrading enzyme in accordance with the process of the EP '343 reference without producing a soy protein material having the claimed levels of RNA (37 CFR §1.132 Declaration of Theodore Wong, attached as Appendix C).

In the Advisory Action of October 14, 2003, the final rejection of the claims on the basis of inherent anticipation by the EP '343 reference was maintained. The ground for maintaining the rejection was that "the soy protein materials of the cited reference have been treated with a phytase and acid phosphatase which degrade RNA present in soy protein. Therefore, a soy protein material containing at most 4000 mg/kg RNA is a necessary consequence of such treatment." As far as the deliberate intent of the reference, the Patent Office argued that "treatment with a phytase and acid phosphatase" is "deliberately intended as disclosed by the prior art reference."

One issue framed by the Patent Office's answer in the Advisory Action is: "what is a necessary consequence (of what was deliberately intended by a reference) sufficient to establish an inherent anticipation". *See Mehl/Biophile International Corp. v.*

Milgraum, 52 USPQ2d 1303, 1307 (CAFC 1999)(for a claim element to be anticipated inherently by a reference the element must be a necessary consequence of what was deliberately intended as disclosed in the prior art reference). Applicants contend that a claim element must be a necessary consequence of what the reference teaches as a whole to be inherently anticipated by the reference. The deliberate intent of the reference, what the reference teaches can be achieved by the disclosure of the reference, guides the inquiry of what the reference teaches as a whole in order to determine whether a claim element is inherently anticipated. The Patent Office contends that the claim element is inherently anticipated if the claimed element is a necessary consequence of any deliberately intended disclosure in the reference (where the deliberately intended disclosure does not mention the claimed element), regardless whether other deliberately intended disclosures in the reference for accomplishing the goal of the reference do not necessarily result in the claimed element.

It is irrelevant to an inquiry of inherent anticipation, however, that one method among other methods of practicing a process as disclosed by a reference may inherently yield a claimed element where the other methods do not inherently yield the claimed element, even if the one method is the preferred method of practicing the process. Inherency may not be established by probabilities or possibilities—the mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). Occasional results are not inherent. *Mehl/Biophile International Corp.* 52 USPQ2d at 1306. See also *Trintec Industries Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597, 1599 (CAFC 2002); *In Re Robertson*, 49 USPQ2d 1949, 1950-51 (CAFC 1999); *Rosco Inc. v. Mirror Lite Co.*, 64 USPQ2d 1676, 1679-81 (CAFC 2002); and *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1748-1750 (CAFC 1991).

The EP '343 reference is directed to a process for producing phytate-free or low phytate soy proteins and the resulting phytate-free or low phytate soy protein products. The '343 reference clearly states the deliberate intent of the disclosed process:

“Stated most simply, in its broadest terms the present invention comprises:

- (a) suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation comprising one or more phytate-degrading enzymes; and
- (b) isolating the resulting phytate-free or low phytate soy protein.”

One can practice the disclosure of the EP '343 reference with "one or more phytate-degrading enzymes," which are disclosed in the reference to include phytase and acid phosphatase enzymes (EP 0 380 343 page 6, line 19).

The EP '343 reference can be practiced to produce a low phytate soy protein material according to the process disclosed by the reference without producing a soy protein material containing at most 4000 mg/kg of RNA by utilizing a phytase enzyme instead of an acid phosphatase enzyme. Applicants have shown that a phytase enzyme, Natuphos® available from BASF Aktiengesellschaft, reduces phytate in a soy protein material in accordance with the disclosure of the reference but does not reduce RNA concentrations in the soy protein material and does not produce a soy protein material containing at most 4000 mg/kg of RNA. See Appendix C, 37 C.F.R. §1.132 Declaration of Theodore Wong.

The claims 79-86, therefore, are not inherently anticipated by the EP '343 reference in accordance with the law as set forth in *In re Oelrich and Mehl/Biophile International Corp.* According to that law, inherency cannot be established by probabilities or possibilities, and the mere fact that the claimed element of a soy protein material containing at most 4000 mg/kg of RNA may occur from a given set of circumstances while practicing the phytate-reducing process of the EP '343 patent does not render the claimed element inherently anticipated. The process of the EP '343 patent can clearly be practiced to produce the desired result (ie. the intent) of the process, a low phytate soy protein material, without producing the claimed element of a soy protein material containing at most 4000 mg/kg of RNA.

A second issue raised by the Patent Office's rejection of the claims is whether the claim element "a soy protein material containing at most 4000 mg/kg of ribonucleic acids" is produced as a necessary consequence of practicing the EP '343 reference even if an acid phosphatase enzyme is used to degrade phytates and phytic acid in accordance with the process of the reference. The process as disclosed by the EP '343 reference can be practiced with an acid phosphatase enzyme preparation without producing a soy protein material containing at most 4000 mg/kg of ribonucleic acids. As shown in the Second Declaration of Theodore Wong under 37 CFR §1.132 (attached as Appendix D), a soy protein material can be treated with a FINASE® enzyme preparation containing an

acid phosphatase under conditions disclosed in the EP '343 reference without producing a soy protein material containing at most 4000 mg/kg of ribonucleic acids. Specifically, a soy protein curd material treated with a FINASE[®] enzyme preparation containing an acid phosphatase at a pH of 5.1 (within the range of pH 2.0 – 6.0 set out in EP '343, page 7, line 2); at a temperature of 38°C (within the range of 20°C - 60°C, EP '343, page 7, line 4); and for a time period of 2 hours (within the range of 1 – 8 hours, EP '343, page 4, lines 22 and 47; page 5 lines 2, 16, 26 and 43) produced a soy protein material containing 6419 mg/kg of ribonucleic acids. Clearly, therefore, the claimed element of “a soy protein material containing at most 4000 mg/kg ribonucleic acids” is not inherently produced by the process of the EP '343 reference, even if the process is limited to the use of an acid phosphatase enzyme to degrade phytates and phytic acid in a soy protein material.

Furthermore, the Patent Office has not met its burden to provide sufficient basis for considering that practice of the process disclosed by the EP '343 inherently results in the claimed compositions of claims 79-86. In relying upon the theory of inherency, the Patent Office must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessary flows from the teachings of the prior art. *Ex parte Levy*, 17 USPQ2d 1461 (BPAI 1990). The Patent Office has merely established that the reference teaches treating a soy protein material with FINASE[®], an acid phosphatase containing enzyme preparation. The Patent Office has not provided a basis in fact or technical reasoning to support the allegation that treatment of a soy protein material with an acid phosphatase enzyme will always, necessarily result in a soy protein material containing at most 4000 mg/kg of ribonucleic acids under all conditions disclosed in the process of the EP '343 reference.

As shown above, the Patent Office has failed to establish that claims 79-86 are explicitly or inherently anticipated by the EP '343 reference. The claim element of a soy protein material containing at most 4000 mg/kg ribonucleic acids, contained in all the claims, is not explicitly disclosed or inherently produced by the process disclosed in the EP '343 reference. The EP '343 reference discloses that phytase enzymes, as well as acid phosphatase enzymes, are effective to practice the desired phytate-reducing effect in a soy protein material. Phytase enzymes, however, are ineffective to reduce ribonucleic

acid content in a soy protein material (typically 16,000 mg/kg to 23,000 mg/kg in a conventional soy protein material), therefore, a soy protein material containing at most 4000 mg/kg of ribonucleic acids is not a necessary consequence of practicing the EP '343 reference. Even if an acid phosphatase enzyme is utilized in the process of the EP '343 reference, a soy protein material containing at most 4000 mg/kg of ribonucleic acids is not a necessary consequence of the EP '343 process since the process conditions disclosed in the EP '343 reference may result in a soy protein material having reduced levels of ribonucleic acids where the ribonucleic acid level in the soy protein material is above 4000 mg/kg. Furthermore, the Patent Office has not established any basis in fact or technical reasoning that utilizing an acid phosphatase enzyme in accordance with the process of the EP '343 reference will necessarily result in a soy protein material containing at most 4000 mg/kg of ribonucleic acids. As such, a soy protein material containing at most 4000 mg/kg of ribonucleic acid cannot be a necessary consequence of the process disclosed in the EP '343 reference, and the EP '343 reference cannot anticipate claims 79-86 either inherently or explicitly.

The §103(a) rejection

Claims 79-86 stand rejected under 35 U.S.C. §103(a) as being obvious over EP 0 380 343.

In the Office Action of July 1, 2003, claims 79-86 were finally rejected as being obvious over the EP '343 reference in the alternative to being anticipated by the reference, allegedly because any difference between the claimed invention and the disclosure of the reference would be considered so slight as to render the claims *prima facie* obvious over the reference. The Patent Office alleged that it would have been obvious to one skilled in the art *at the time of the claimed invention* to degrade ribonucleic acids along with phytic acid because the enzymatic activity of the FINASE enzymes (commercial enzymes having acid phosphatase activity) disclosed in the reference could be expected to degrade RNAs as well as phytate.

In their response after final rejection of August 7, 2003, the Applicants responded that claims 79-86 (erroneously identified as claims 1, 3-36) were not obvious over the '343 reference because the '343 reference provided no teaching at all regarding degrading ribonucleic acids in any material. Applicants pointed out that no proof was provided by

the Patent Office that, at the time of the invention, one skilled in the art would expect FINASE enzymes to degrade RNA, and that it was improper to retroactively view the disclosure of the reference through the lens of the invention to establish such proof. As such, Applicants averred that one skilled in the art would learn nothing from the cited reference regarding RNA levels in soy protein materials, so the claimed element of a soy protein material containing at most 4000 mg/kg of RNA is not *prima facie* obvious from the EP '343 reference.

In the Advisory Action of October 14, 2003 the obviousness rejection over the EP '343 reference was upheld. The Patent Office stated that the basis for obviousness is well established by what is conventional and well known in the art, as well as what is specifically taught by the cited prior art. The Patent Office then noted that it was well known that soy protein contained RNA at the time of the invention. Finally, the Patent Office concluded that the cited prior art teaches an acid phosphatase which will degrade polymeric ribonucleoside-containing compounds such as RNA.

The Patent Office's obviousness analysis, however, is missing a key link. In summary, the Patent Office's position is that 1) soy protein was known to contain RNA at the time of the invention; 2) the EP '343 reference discloses treating a soy protein material with an acid phosphatase containing enzyme (FINASE®) to degrade phytates and phytic acid; and therefore 3) one skilled in the art would find it obvious to degrade RNA in a soy protein material with an acid phosphatase enzyme to produce a soy protein material containing at most 4000 mg/kg of RNA because the EP '343 patent discloses treating a soy protein material (recognized as containing RNA) with an acid phosphatase enzyme. The key missing link in the Patent Office's chain of logic, however, is the subject matter of the present invention—that acid phosphatase enzymes are effective to degrade RNA. One cannot progress in a logical progression from steps 1 and 2 above of the Patent Office's position to step 3 without recognizing that acid phosphatase enzymes degrade RNA.

At the time of the invention, however, one skilled in the art was not aware that acid phosphatase enzymes degrade RNA. One of skill in the art at the time of the invention did recognize that there is a significant difference between enzymatic degradation of phytates (non-polymeric mono-phosphoester phosphate containing

compounds) and enzymatic degradation of ribonucleic acids (polymeric diphosphoester-linked nucleotides). As shown in Leach et al, *Am J Clin Nutr*, 1995; 61:1224-30 (particularly p. 1224, 2d col. 1st paragraph; and p. 1226, Figure 1) (attached as Appendix E), at the time of the invention one skilled in the art did not expect phosphatases to degrade polymeric nucleotides such as ribonucleic acids, but rather expected polymeric nucleotides to be degraded by phosphodiesterase enzymes such as ribonucleases and deoxyribonucleases (nucleases). As shown by Leach et al one skilled in the art would expect phosphatases to be effective to degrade only mono-phosphoester compounds such as monomeric nucleotides and phytates. In short, at the time of the invention one skilled in the art recognized that ribonucleic acids are a fundamentally different type of compound from phytates, and did not expect a phosphatase to degrade ribonucleic acids.

The Patent Office has not provided any evidence that it was known prior to the invention that an acid phosphatase will degrade polymeric ribonucleoside-containing compounds such as RNA, so that a soy protein material containing at most 4000 mg/kg of RNA could be produced by degrading RNA in the soy protein material with an acid phosphatase. The Patent Office has only made the unsubstantiated statements that “Finase...can be expected to degrade RNAs”(Final Rejection of July 1, 2003, page 4, line 12) and “the cited prior art teaches an acid phosphatase which will degrade polymeric ribonucleoside-containing compounds such as RNA” (Advisory Action, page 3, lines 5-7). The only apparent source for these statements is the Applicants’ disclosure in the present invention. No other proof has been offered by the Patent Office that one skilled in the art at the time of the invention would expect an acid phosphatase (or FINASE[®]) to degrade RNAs. The Patent Office appears to be retroactively viewing the disclosure of the reference through the lens of the invention—improper hindsight that cannot be used to establish a *prima facie* case of obviousness. See In re Decbiczak, 50 USPQ2d 1614 (Fed.Cir. 1999). As such, the Patent Office has failed to establish a *prima facie* case of obviousness of claims 79-86 over the EP ‘343 patent.

The §103(a) rejection of claims 79 and 86 as obvious over EP 0 380 343 in view of U.S. Patent No. 6,313,328 to Ulrich et al.

U.S. Patent No. 6,313,328 to Ulrich et al. (attached as Appendix F) discloses a method of extraction of corn oil from flaked corn grain. The corn oil may be extracted from corn grain using extracting equipment used for extracting oil from soy flakes. The phosphorus content of the corn oil in Example 1 is 365 ppm. EP 0 380 343 is discussed above.

Claim 79 is discussed above. Claim 86 provides the composition of claim 79 in which the soy protein material contains less than 3000 ppm phosphorus.

There is no suggestion to combine the cited references to arrive at the presently claimed invention. Case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham et al v. John Deere Company of Kansas City et al*, 148 USPQ 459, 467 (U.S. 1966) ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.").

One skilled in the art would have no reason to combine the teachings of the EP 0 380 343 patent and Ulrich et al. to arrive at the claimed invention. The '343 patent is directed to producing a soy protein material containing reduced levels of phytates and phytic acid. The soy protein material is a soy protein isolate or a soy protein concentrate—soy protein materials that are produced from defatted soy flakes (*see* EP 0 380 343, page 6, lines 14-15). In the art of soy processing “defatting” is equivalent to “deoiling”, therefore, the soy protein concentrates and soy protein isolates utilized in the process of the '343 patent have had oil removed therefrom.

Ulrich is directed to a method for producing corn oil from corn meal by separating a corn oil from a high oil corn meal (*see* abstract of U.S. Patent No. 6,313,328 to Ulrich et al.). The corn oil produced by the method of Ulrich has a phosphorus content of less than about 500 parts per million (col. 2, lines 24-27, U.S. Patent No. 6,313,328 to Ulrich et al.). The corn meal resulting from separating the oil from the high oil corn meal is the protein containing product of the process of Ulrich et al. (col. 2, lines 14-23), and no disclosure is provided in Ulrich et al. regarding the phosphorus content of the residual corn meal after separation of corn oil from the meal.

One skilled in the art would have no reason to combine the teachings of the EP 0 380 343 and Ulrich et al references because: 1) the EP '343 reference refers to a method for processing a soy protein material and Ulrich et al refers to a method for processing a corn material, and soy and corn processing are substantially different (*see* Ulrich et al., col. 3, lines 47-57); 2) the EP 0 380 343 reference refers to a method for processing a defatted (deoiled) soy protein material, a substantially oil-free material, to produce a substantially oil-free soy protein product and the Ulrich et al. references refers to a method for extracting corn oil from a high oil corn meal to form a corn oil product; and 3) the disclosed processes are so different that there is no teaching in one reference that is applicable in the method of the other reference.

Furthermore, even if the references could be combined, the combined references have little to do with the claimed compositions. The claimed compositions are directed to a soy protein material containing at most 4000 mg/kg of RNA. Neither of the references discloses RNA at all, therefore, one skilled in the art would find no teaching leading to the claimed compositions of claims 79 and 86. Further, claim 86 is directed to

a soy protein material containing at most 4000 mg/kg RNA where the soy protein material contains less than 3000 ppm phosphorus. Ulrich et al disclose a corn oil containing less than 3000 ppm phosphorus, but it is unclear how that would teach a person skilled in the art to produce a soy protein material containing less than 3000 ppm phosphorus.

The §102(e) rejection of claims 79-86 as anticipated by U.S. Patent No. 6,313,273 to Thomas et al.

U.S. Patent No. 6,313,273 to Thomas et al. (attached as Appendix G) was filed on August 25, 1999 and issued on November 6, 2001. As shown in the Theodore M. Wong Declaration Under 37 CFR §1.131 (attached as Appendix H), Applicants had conceived and actually reduced to practice the invention of claims 79-86 before the filing and issue of the Thomas et al patent, and, therefore, the Thomas et al patent is art that may not be cited against claims 79-86 under 35 U.S.C. §102(e). As such, claims 79-86 are not anticipated by U.S. Patent No. 6,313,273 to Thomas et al.

The §103(a) rejection of claims 79-86 as obvious over U.S. Patent No. 6,313,273 to Thomas et al.

As shown above, U.S. Patent No. 6,313,273 to Thomas et al is not art that may be cited against claims 79-86. As such, claims 79-86 are not obvious over the disclosure U.S. Patent No. 6,313,273 to Thomas et al.

The §103(a) rejection of claims 79-86 as obvious over U.S. Patent No. 6,313,273 to Thomas et al in view of U.S. Patent No. 6,313,328 to Ulrich et al.

As shown above, U.S. Patent No. 6,313,273 to Thomas et al, is not art that may be cited against claims 79 and 86. As such, claims 79 and 86 are not obvious over the disclosures of U.S. Patent Nos. 6,313,273 to Thomas et al and U.S. Patent No. 6,313,328 to Ulrich et al.

CONCLUSION

In view of the foregoing, Applicant submits that claims 79-86 are patentable over European Patent No. 0 380 343 A2; U.S. Patent No. 6,313,328 to Ulrich et al.; and U.S. Patent No. 6,313,273 to Thomas et al.

Respectfully submitted,
SOLAE, LLC.

APPENDIX A

CLAIMS

79. (previously added) A composition comprising, a soy protein material containing at most 4000 mg/kg ribonucleic acids and being substantially devoid of ribonuclease enzymes.
80. (previously added) The composition of claim 79 wherein said soy protein material is a soy protein isolate or a soy protein concentrate.
81. (previously added) The composition of claim 79 wherein said soy protein material contains less than 2000 mg/kg ribonucleic acids.
82. (previously added) The composition of claim 79 wherein said soy protein material contains less than 1500 mg/kg ribonucleic acids.
83. (previously amended) The composition of claim 79 wherein phytic acid comprises at most 0.45% of said soy protein material by weight.
84. (previously amended) The composition of claim 83 wherein phytic acid comprises at most 0.2% of said soy protein material by weight.
85. (previously amended) The composition of claim 84 wherein phytic acid comprises at most 0.1% of said soy protein material by weight.
86. (previously amended) The composition of claim 79 wherein said soy protein material contains less than 3000 ppm phosphorus.

APPENDIX B



Europäisches Patentamt
European Patent Office
Office européen des brevets

Publication number:

0 380 343
A2

EUROPEAN PATENT APPLICATION

Application number: 90300800.1

Int. Cl.³: A23J 1/14, A23L 1/211

Date of filing: 25.01.90

Priority: 25.01.89 US 301563
29.09.89 US 414014

Date of publication of application:
01.08.90 Bulletin 90/31

Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

Applicant: ALKO LIMITED
Salmisaarenranta 7
SF-00180 Helsinki(FI)

Inventor: Simell, Maarit
Emannankuja 2 H
SF-01670 Vantaa(FI)
Inventor: Elovalio, Minna
Vanhalistentie 12 E
SF-00420 Helsinki(FI)
Inventor: Varra, Martti
Aino Ackentie 10 A
SF-00400 Helsinki(FI)
Inventor: Varra, Timo
Itäinen puistotie 16
SF-00140 Helsinki(FI)

Representative: Sheard, Andrew Gregory et al
Kilburn & Strobe 30, John Street
London WC1N 2DD(GB)

Method for production of phytate-free or low-phytate soy protein isolate and concentrate.

A method by which phytate-free or low-phytate soy protein isolates and concentrates may be prepared is disclosed along with the phytate-free or low-phytate soy protein isolates and concentrates produced. The method involves using a phytate-degrading enzyme at a pH of from 2.0 to 6.0 at a temperature of from 20°C to 55°C.

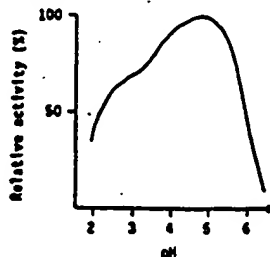


Figure 1. Effect of pH on the activity of phytate-degrading enzymes

temperature: 40 °C
reaction time: 15 min.
buffers: 0.2 M citrate,
pH 3.5 - 6.5
0.2 M glycine-HCl
pH 2.0 - 3.0

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METHOD FOR PRODUCTION OF PHYTATE-FREE OR LOW-PHYTATE SOY PROTEIN ISOLATE AND CONCENTRATE

The present invention relates to novel methods and processes by which phytate-free or low-phytate soy protein isolates and concentrates may be prepared. The invention further relates to phytate-free or low-phytate soy protein isolates and concentrates produced according to the methods and processes of the present invention.

Phytic acid is present in soy beans as in many other plant seeds. Phytic acid in plants appears in the form of calcium, magnesium, and potassium salts, which in general are called phytin. A large part of the phosphorus content of seeds is stored in these compounds. For example, about 70% of the total phosphorus in soy beans is accounted for by phytin. When the terms phytate or phytic acid are used herein, it is intended to include salts of phytic acid and molecular complexes of phytic acid with other soy bean constituents.

Phytic acid tends to form complexes with proteins and multivalent metal cations. Phytic acid complexes decrease the nutritional quality of soy protein (for review, see e.g., Reddy et al., *Adv. Food Res.* 28:1-92 (1982); Cheryan, *CRC Crit. Rev. Food Sci. Nutr.* 13:297-335 (1980)). Phytic acid, because it interacts with multivalent metal cations, interferes with the assimilation by animals and humans of various metals such as calcium, iron, and zinc. This may lead to deficiency disorders, especially for vegetarians, elderly people and infants.

Phytic acid also inhibits various enzymes in the gastrointestinal tract, including pepsin and trypsin, and decreases the digestibility of soy protein. In addition, the phosphate present in phytic acid is not available to humans. Moreover, the presence of a relatively large amount of such unavailable phosphorus in infant food may lead to inadequate bone mineralization.

In typical commercial soy protein isolation processes, defatted soy flakes or soy flour are extracted at pH values between 8.0 and 10.0 to solubilize proteins. The slurry is centrifuged to separate the insoluble part from the solution. The major fraction is recovered from the solution either by precipitating at a pH near the isoelectric point of the protein (4.5), separating it by centrifugation, washing the precipitate with water, redispersing it at pH 7, and spray-drying it (see, e.g., U.S. Pat. Nos. 3,001,875 and 3,397,991). In such processes, phytic acid will follow the protein, and tends to concentrate in the resulting soy protein product. The phytic acid content of commercial soy protein isolates is about 2-3%, whereas soy beans contain 1-2% phytic acid.

Because of the world-wide importance of soy beans as a food source, there have been many attempts to devise ways in which to reduce the phytate concentration of soy protein isolates and concentrates.

Thus, various chemical and physical treatments and plant phytases, either indigenous phytase or wheat phytase, have been used for preparing low-phytate soy protein isolates from soy beans. Fermentative methods with living molds have also been studied as ways of decreasing the phytic acid content of soy protein isolates.

None of these methods, however, provides a quick and economical method for production of phytate-free soy protein isolates without adversely affecting the functional properties of the protein.

Bolley et al., U.S. Pat. 2,732,395 describes a method for separation of phytic acid from various oil seeds with an aqueous extraction at a pH near the isoelectric point of the protein (about 4.5). Phytic acid is partly dissolved at this pH and is recovered. Protein is recovered by solubilizing it at alkaline pH, separating the insoluble portion, and precipitating the protein at a pH near the isoelectric point. The resulting protein fraction contained as much as 4% organic phosphorus.

McKinney et al., *J. Biol. Chem.* 178:117-132 (1949), note that phytic acid dissociates from soy protein at pH values between 11.0 and 11.5, and forms a precipitate that may be removed by centrifugation.

Goodnight et al., U.S. Pat. 4,072,670, observe that an alkali-stable complex is formed between protein and phytic acid in the acidic conditions used by Bolley et al. In an attempt to overcome this disadvantage, they describe precipitation of the phytate at pH values a little higher than those described by McKinney et al., i.e., pH values between 11.6 and 14. Phytate is then separated from the protein prior to protein precipitation at the protein isoelectric point (pH 4.5). One disadvantage of this process is that exposure of proteins to such an extremely alkaline pH adversely affects the nutritive value of proteins. Also, there is a tendency to increase the undesirable formation of lysinoalanine. In addition, commercial continuous centrifuges are unable to separate the very light phytate precipitate formed at such a high pH.

deRham, UK Pat. 1 574 110, discloses methods by which the phytic acid content of a soy protein isolate can be decreased from 2% to 0.6%, when protein precipitation from neutral soy extract (extracted at pH 8.0) is performed at pH 5.7 instead of pH 4.5. When soy proteins are extracted at pH 2.5 and recovered

at pH 4.5, the phytic acid content is reported to be 1.7%. By performing the precipitation at pH 5.5, the phytic acid content was reportedly decreased to 0.7%. The phytic acid concentration of the isolate could be decreased to 0.2% by extracting the protein at pH 11.5 and recovering it at pH 5.5. However, these methods suffer from the drawback that the protein yield is decreased by as much as 20%, which renders them commercially impracticable.

deRham and Jost, *J. Food Sci.* 44:596-600 (1979), observe that calcium ions enhance the precipitation of soy protein at pH 11.5. Very low phytic acid concentrations could be achieved by extraction with 10% NaCl, but these methods produced an isolate which is effectively unusable without desalting by dialysis or ultrafiltration. Moreover, also the protein yield according to these methods is low.

Iacobucci et al., U.S. Pat. 3,736,147, disclose a method of reducing phytate concentration in soy protein involving various chemical treatments in combination with ultrafiltration. The chemical treatments include hydrolysis of phytic acid by indigenous phytase at neutral pH, ultrafiltration in the presence of calcium ions at low pH, or the use of EDTA at high pH. These methods have several disadvantages. Soy globulins are known to dissociate into subunits and to be denatured at such low pH values. The use of calcium ions at low pH values requires an additional ultrafiltration step for salt removal. The high temperature (65°C) in the phytase method may decrease the solubility of the protein on either side of the isoelectric point. The lowest phosphorous content achieved is not less than 0.2%, which corresponds to 0.7% phytic acid. The methods are also very time-consuming (18-48 h ultrafiltrations).

Puski et al., UK Pat. Appl. GB 2,180,241, disclose a soy protein preparation method in which proteins are extracted at a pH of 8 to 10 and at a temperature above 65°C. The protein product contains less than about 0.3% phytic acid. Again, however, such high temperatures may adversely affect the solubility and other functional properties of the proteins.

Brooks and Morr, *J. Food Sci.* 47:1280-1282 (1982), disclose a method for phytate removal from soy protein isolates using ion exchange treatments. A combination of cation and anion exchange processes is required for effective phytate removal. A dialysis step is used to remove other nonprotein components. This method, however, would be unacceptably complex and expensive for use on a commercial scale.

Enzymes, such as phytase, also have been used in the preparation of soy protein isolates. For example, McCabe, U.S. Pat. 3,733,207, describes the preparation of a soluble protein fraction having a decreased phytic acid content. Proteins are solubilized in alkaline conditions, and wheat phytase is added after lowering the pH to about 5. The protein fraction not precipitated at pH 4.5 is recovered. The resulting protein, because of its solubility in acidic conditions, is suitable for carbonated beverages. The enzyme treatment is long, however, requiring 24-36 hours. The phytic acid content of the protein is not reported.

Japanese Appl. 50,130,800, assigned to Asahi Chemical Ind. Kk, describes a process by which 60% of the phytic acid in aqueous plant seed extracts could be removed by a combination of wheat phytase and cation exchange resin treatment. The lowest phosphorous content of soy protein achieved is as high as 0.24%, which corresponds to 0.85% phytic acid.

Various fermentation processes have been proposed for improving the odor, flavor or digestibility of soy products. Typical fermentation processes, however, require an extensive amount of time, usually 24 hours or longer, and substantially alter the functional or physical characteristics of the protein.

Friend et al., U.S. Pat. 4,642,236, describe a quick method for improving soy product flavor, involving contacting soy protein with living mold pellets of *Aspergillus* or *Rhizopus* species. However, large amounts of mold - as much as 1 to 10 g - are needed per 100 g of protein on a dry weight basis for effective results in treating an aqueous slurry. Also, sulphite materials conventionally used in the extraction processes adversely affect the activity of the mold.

The use of phytase has been described in the treatment of soluble soy protein contained in soy milk. In preparing soy milk, soy beans are soaked overnight, disrupted and filtered. This filtrate is termed soy milk. After filtration, the soy milk typically is cooked to remove off-flavor compounds.

Anno et al., *Nippon Shokuhin Kogyo Gakkaishi* 32(3):174-180 (1985), report elimination of 90% of the phytate contained in commercial soy bean milk with wheat phytase. Nippon Shinyaku, Japanese Appl. 59,166,049, report a method of decomposing phytic acid in soy bean milk with wheat phytase, using free and immobilized phytases. Fujiwara et al., (Reports of Research Laboratory, Snow Brand Milk Products Co. No. 83 (1986) 31-41, Ref. FSTA 19 (1987) 9J118), report improvements in soy milk digestibility with *Rhizopus* sp. phytase treatment.

Microbial phytases have also been tested in decreasing the phytic acid content of feedstuffs without further processing to protein concentrates or isolates (Han and Wilfred, *J. Agric. Food Chem.* 36:259-262 (1988)). Autoclaving (121°C, 1 h) facilitates the degradation of phytic acid by *Aspergillus ficuum* phytase (85% degraded). Such high temperatures, however, alter the functional properties of the resulting protein and reduce its nutritional value.

The preceding discussion illustrates that considerable efforts have been expended to develop methods to reduce the phytic acid content of soy protein. These methods, however, have suffered from various drawbacks, including inefficient phytic acid reduction, high cost, long treatment time requirements, unacceptable alterations of the treated protein, and incompatibility with commercial soy protein processing techniques.

As a result, there continues to be a need for an improved method of producing phytate-free or low-phytate soy protein isolates and concentrates which avoids these drawbacks, while allowing soy protein production on a practical commercial scale.

The present invention relates to novel methods and processes by which phytate-free or low-phytate soy protein isolates and concentrates may be prepared. The invention further comprises phytate-free or low-phytate soy protein isolates and concentrates produced according to the methods and processes of the present invention.

In a first aspect of the present invention there is provided a method of reducing or eliminating phytate in a composition comprising soy bean protein, the method comprising contacting a phytate degrading enzyme with the composition at a pH of from 2.0 to 6.0 at a temperature of from 20°C to 60°C. The method preferably has one or more of the following features:

- a) the composition is a soy protein isolate or soy protein concentrate;
- b) the temperature is from 40-55°C;
- c) the pH is from 4.5 to 5.5;
- d) the enzyme is added to the composition in the form of an enzyme preparation free of living matter, for example cells, such as microorganisms;
- e) maintaining contact between the soy bean protein and enzyme for from 1.0 to 8.0 hours, preferably from 2 to 6 hours.

The enzyme preparation preferably comprises a phytase enzyme produced by *Aspergillus niger* and/or is substantially cell free. Suitably the enzyme preparation contains cellulase and/or has low proteolytic activity which is particularly suitable for soy protein. A particularly suitable enzyme preparation is that sold under the trade mark FINASE[®] S by Alko Ltd., Helsinki, Finland.

A second aspect of the present invention relates to a method for producing an essentially phytate-free or low-phytate soy protein isolate or concentrate comprising:

- a) adding an enzyme preparation of microbial origin comprising at least one phytate degrading enzyme to a particulate soy bean water slurry;
- b) allowing the phytate degradation to take place at a pH value of from 2.0 to 6.0, and at a temperature from 20°C to 55°C; and
- c) isolating the resulting phytate-free or low-phytate soy protein.

A third aspect of the present invention is a method of substantially eliminating phytate from soy protein isolate or concentrate comprising:

- a) adding to a phytate-containing soy protein isolate or concentrate an enzyme preparation of microbial origin comprising at least one phytate degrading enzyme; and
- b) allowing phytate degradation to take place at a pH of from 2.0 to 6.0, and at a temperature of from 20°C to 55°C.

A fourth aspect of the present invention provides a method of producing an essentially phytate-free or low-phytate soy protein isolate, comprising:

- a) suspending coarsely milled defatted soy particulate in an aqueous medium, suitably water, to form a suspension;
- b) adjusting the pH of the suspension of step a) to from 2.0 to 6.0, preferably about pH 5.0;
- c) introducing into the suspension of step b) a phytase reducing amount of FINASE[®] S;
- d) incubating the suspension of step c) for from 1.0 to 8.0 hours (eg. 2-6 hours) at from 20°C to 50°C;
- e) adjusting the pH of the suspension of step d) to about 9.0, and incubating the adjusted suspension for about 1 hour at room temperature;
- f) separating the insoluble fraction from the suspension of step e); and
- g) separating the soluble soy protein from the suspension of step f) thereby producing an essentially phytate-free or low-phytate soy protein isolate.

A fifth aspect of the present invention encompasses producing an essentially phytate-free soy protein isolate or concentrate, or a soy protein isolate having a reduced phytate concentration, comprising:

- a) suspending an amount of commercial soy protein isolate in an aqueous medium, to form a suspension;
- b) adjusting the pH of the suspension of step a) to from 2.0 to 6.0, preferably from 4.5 to 5.5, and more preferably about pH 5.0;

- c) introducing into the suspension of step b) a phytase reducing amount of FINASE[®] S;
- d) incubating the suspension of step c) for from 1.0 to 8.0 hours, eg. 2-6 hours, at from 20°C to 65°C, preferably about 40°C;
- e) adjusting the pH of the suspension of step d) to about 4.5; and
- f) separating the soy protein from the suspension of step e); thereby producing an essentially phytate-free soy protein isolate or concentrate, or a soy protein isolate having a reduced phytate concentration.

A sixth aspect of the present invention relates to an essentially phytate-free or low-phytate soy protein isolate or concentrate comprising:

- a) extracting the protein from a defatted particulate soy bean aqueous suspension at a pH value of from 8.0 to 10.0;
- b) removing any insoluble material from the suspension of step a);
- c) adjusting the pH of the suspension of step b) to from 2.0 to 6.0, preferably from 4.5 to 5.5 and suitably about pH 5.0;
- d) introducing into the suspension of step c) a phytase reducing amount of FINASE[®] S; and
- e) incubating the suspension of step d) for from 1.0 to 8.0 hours at from 20°C to 55°C, preferably about 40°C; thereby producing an essentially phytate-free or low-phytate soy protein isolate or concentrate.

A seventh aspect of the present invention relates to an essentially phytate-free or low-phytate soy protein isolate or concentrate comprising:

- a) extracting the protein from a defatted particulate soy bean aqueous suspension at a pH value of from 8.0 to 10.0;
- b) removing any insoluble material from the suspension of step a);
- c) adjusting the pH of the suspension of step b) to from 2.0 to 6.0, preferably from 4.5 to 5.5, and suitably about pH 5.0;
- d) introducing into the suspension of step c) a phytase reducing amount of FINASE[®] S;
- e) incubating the suspension of step d) for from 1.0 to 8.0 hours, eg. about 4 hours, at from 20°C to 55°C, preferably about 40°C;
- f) adjusting the pH of the suspension of step e) to the isoelectric point of the protein to precipitate the protein; and
- g) separating the precipitated protein of step f) to produce a precipitated protein and an aqueous solution; thereby producing an essentially phytate-free or low-phytate soy protein isolate or concentrate.

In an eighth aspect of the present invention there is provided a method of producing an essentially phytate-free or low-phytate soy protein isolate or concentrate comprising:

- a) extracting the protein from a defatted particulate soy bean aqueous suspension at a pH value of from 8.0 to 10.0;
- b) removing any insoluble material from the suspension of step a);
- c) adjusting the pH of the suspension of step b) to the isoelectric point of the protein to produce a precipitated protein and an aqueous solution;
- d) separating the precipitated protein of step c) from the aqueous solution of step c);
- e) redispersing the protein of step d) in an aqueous solution;
- f) adjusting the pH of the solution of step e) to from 2.0 to 6.0, for example about pH 5.5;
- g) introducing into the solution of step f) a phytase reducing amount of FINASE[®] S;
- h) incubating the solution of step g) for from 1.0 to 8.0 hours, preferably from 2 to 6 hours, eg. about 4 hours, at from 20°C to 55°C;
- i) neutralizing the solution of step h); and
- j) spray-drying the solution of step i); thereby producing an essentially phytate-free or low-phytate soy protein isolate and concentrate. Where aqueous suspension, solution or medium is referred to, this is preferably water.

It is preferred that the incubating temperature is about 55°C and/or the separating step comprises centrifugation or drum filtration. However, the separating step may comprise precipitation of the soluble soy protein by adjusting the pH of the suspension to 4.5. Generally the isoelectric point of the protein is about 4.5.

The present invention may thus provide easy and commercially attractive methods for preparing phytate-free and low-phytate soy protein isolates and concentrates. An advantage of the present invention is that these methods can be suitable for integration into commercial soy protein processing techniques, with an attendant improvement in the efficiency and economy of producing this important food source. The phytate hydrolysis may be performed before or after the isolation process or during the isolation process whenever the process conditions (pH and temperature) are adjusted to suit for the phytate degrading

enzyme. The many possible places for the enzyme treatment may make it easy for the manufacturer to adopt the process of the invention to their existing isolation process. Further, the methods of the present invention may not require exposing the soy protein to highly alkaline conditions causing decreased nutritive value in the resulting protein, and which produce a very light, suspended phytate precipitate that cannot be separated by commercial continuous separation equipment.

An additional advantage of the present invention is that the soy protein may not be exposed to high temperatures (eg., above 65°C) which may adversely affect the solubility and other functional properties of the soy protein product. Moreover, the methods of the invention avoid exposing the soy protein to living microorganisms, which may introduce contaminants into the soy protein product. Expensive and time-consuming steps, such as ultrafiltration and ion-exchange treatment, may be avoided by the methods of the present invention.

The present invention may thus provide simple methods for the preparation of low-phytate and phytate-free soy protein products without expensive chemical or physical treatments or equipment. The preferred source of soy proteins, such as soy bean water slurry, is defatted soy bean particulate, such as defatted soy flour, grits, or flakes.

In the various aspects of the present invention, phytic acid is eliminated by means of effective commercially available bulk enzyme compositions. Phytate-degrading enzymes dephosphorylate inositol-hexaphosphate to yield inositol and orthophosphate, several forms of inositolphosphates being the intermediate products. Phytate-degrading enzymes include phytase and acid phosphatases.

Phytase and acid phosphatases are produced by various microorganisms such as *Aspergillus* spp., *Rhizopus* spp., and yeasts (Appl. Microbiol. 16:1348-1357 (1968); *Enzyme Microb. Technol.* 5:377-382 (1983)), and phytase is also produced by various plant seeds, for example wheat, during germination. According to methods known in the art, enzyme preparations can be obtained from the above mentioned organisms. Caransa et al., Netherlands Pat. Appl. 87.02735, found that at the same enzyme dosage phytase from *Aspergillus* spp. degraded phytic acid in corn more efficiently than phytase from wheat.

Particularly preferred for the purposes of the present invention are the Finase enzymes, formerly termed Econase EP 43 enzymes, manufactured by Alko Ltd., Rajamäki, Finland. These are described in U.S. application Serial Number 242,243, filed September 12, 1988.

Microbially produced enzyme preparations may also contain enzymes that degrade additional plant material such as enzymes with cellulase, hemicellulase, and/or pectinase activity. These other activities may contribute to the effects which are obtained by the methods of the invention.

The present invention may provide a method for eliminating phytic acid not only from a solubilized substrate such as soy milk or McCabe's soluble proteins, but also from an insoluble protein-phytic acid complex. This is a particular advantage of the invention, since these complexes have formed a significant problem with respect to obtaining high protein yields with low phytate concentrations. The Finase composition used in the methods of the invention is also capable of degrading phytic acid in the presence of the amount of sulphite materials conventionally used in the extraction procedure.

Stated most simply, in its broadest terms the present invention comprises:

- (a) suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation comprising one or more phytate-degrading enzymes; and
- (b) isolating the resulting phytate-free or low phytate soy protein.

A preferred aqueous medium according to the present invention is water, suitably at neutral pH, but those of skill will recognize that any suitable aqueous medium may be employed with the exercise of routine skill, keeping in mind the particular requirements of the starting soy bean particulate preparation.

In a preferred embodiment of the invention, the soy protein isolation process of step (b) above may include the following:

- (a) extraction of protein from the raw material in alkaline conditions, between pH values 8 and 10;
- (b) separating the insoluble fraction containing carbohydrates by conventional solid separation unit processes such as filtration or centrifugation;
- (c) precipitating soy protein at acidic conditions, between pH values 4.5 and 5.5;
- (d) recovering the proteins by conventional solid separation unit processes;
- (e) washing the proteins with acidic water, at the same pH as used for precipitation; and
- (f) drying the proteins.

The enzyme treatment for phytic acid removal can also be applied to soy protein isolates or concentrates after isolation (see example 4). This treatment may include the following steps:

- (a) suspending the protein isolate or concentrate with water in the presence of an enzyme preparation comprising one or more phytate-degrading enzymes; and
- (b) direct use of the protein slurry in food applications or further handling, e.g., drying of the protein.

The enzyme can also be added directly to food, for example infant formula.

The methods of the present invention may be performed at pH values of from 2.0 to 6.0, such as from 3.5 to 5.5, and preferably from 5.0 to 5.5. Preferred temperatures according to the present invention are from 20°C to 60°C, such as about 40°C or from 50°C to 55°C being more preferred. The methods of the present invention prevent the formation of an alkali-stable protein-phytic acid complex in the acidic conditions described by Goodnight et al.

The amount of Finase enzyme preparation required will depend upon the preparation used, the phytic acid content of the raw material, and the reaction conditions. The right dosage can easily be estimated by a person skilled in the art. Preferably, the enzyme preparation comprises such an amount of one or more phytate-degrading enzymes that the phytic acid in soy beans is substantially degraded. The present invention may provide an easy and commercially attractive method for preparing low-phytate and phytate-free soy protein isolates without exposing the proteins to high alkalinity which decreases their nutritive value and at which a very light, suspended phytate precipitate, which cannot be separated with commercial continuous separators, is formed. It may also provide a method for preparing phytate-free soy protein isolate without exposing the proteins to temperatures above 65°C, which may affect the solubility and other functional properties of the protein. Also unnecessary contact of soy protein with living microorganisms and expensive and time-consuming purification steps, such as ultrafiltration and ion-exchange treatments may not be required.

It is to be understood that preferred features and characteristics as described above are applicable for one aspect of the present invention as they are for another aspect, *mutatis mutandis*.

In the accompanying drawings:

Figure 1 is a graph showing the effect of pH on the activity of Finase composition of phytate-degrading enzymes. The pH effect was measured at 40°C after a 15 minute incubation, in 0.2 M citrate (pH 3.5 - 6.5) and 0.2 M glycine-HCl (pH 2.0 - 3.0) buffers; and

Figure 2 is a graph showing the effect of temperature on the activity of a Finase composition of phytate-degrading enzymes. The temperature effect was measured after a 15 minute incubation in a 0.2 M citrate buffer, pH 5.5.

The invention will now be described by way of examples which are not intended to be limiting on the present invention.

COMPARATIVE EXAMPLE 1

The Activity of Phytate-Degrading Enzymes at Different pH Values and Temperatures

This example shows the effect of pH and temperature on the activity of commercial phytate-degrading enzymes. Finase enzymes of Aiko Ltd., Rajamäki, Finland (Figures 1 and 2).

Phytate-degrading activity was determined by using 1% sodium phytate (Sigma, St. Louis, Missouri) as a substrate. The enzyme reaction was carried out at pH 5.5 and 40°C. Phytate-degrading enzymes release phosphate groups from phytate. The determination of the released inorganic phosphorous is based on the color formed by the reduction of a phosphomolybdate complex.

Figures 1 and 2 show that the Finase enzymes degrade phytate over a broad pH range from 2.0 to 6.0 and at temperatures under 60°C. Optimal and preferred pH ranges are between about 5.0 and about 5.5. Optimal and preferred temperatures are between about 50 and 60°C. Variations from these optimal ranges are, of course, possible, depending upon the particular needs and requirements that will be apparent to those of skill. Such variations are to be understood as being within the intended scope of the present invention.

COMPARATIVE EXAMPLE 2

Production of Low Phytate Soy Protein Isolate on a Laboratory Scale

Twenty g of defatted soy flakes (Unilever, Amsterdam, The Netherlands) were milled coarsely and suspended with 300 ml of water. The pH was adjusted to 5.0 and an amount of Finase[®] S was added to the slurry. Phytate-degrading activities are a major component of this enzyme preparation. In the control test no

enzyme was added. Suspensions were incubated for 4 hours in a shaker at 40° C.

The enzyme dosages are presented as phytate-degrading units/g flakes. One phytate-degrading unit (1 PU) is the amount of enzyme which liberates 1 nmol of inorganic phosphorous from sodium phytate per minute under standard conditions (40° C, pH 5.5).

After the enzyme treatment, the pH was adjusted to 9.0 and the suspension was incubated for 1 hour at room temperature. The insoluble fraction was removed by centrifugation. The proteins were precipitated from the supernatant by adjusting the pH to 4.5. The precipitate was recovered by centrifugation and freeze-dried. Protein yield and phytate contents of the protein fraction were determined.

For determination of the phytate content, the protein fraction was extracted with an acidic liquid for 30 minutes at room temperature. Phytic acid was then precipitated from the clear supernatant with ferric chloride. Ferric ions were removed by precipitation with sodium hydroxide. Phytate was determined by HPLC (High Performance Liquid Chromatography) using sodium phytate as a standard. Table 1 shows the residual phytic acid content of the proteins and the protein yields (dry weight basis).

TABLE 1

Phytate Concentration and Protein Yield Achieved by Soy Protein Isolation According to the Invention on a Laboratory Scale		
Finase dosage PU/g soy flakes	Phytic acid %	Protein yield %
0	1.9	25
500	0.6	26
750	0.0	24

Table 1 shows that by using the process of the invention phytate-free soy protein isolates can be achieved while maintaining high protein yields.

COMPARATIVE EXAMPLE 3

Production of Low Phytate Soy Protein Isolate on a Pilot Scale

Fifteen kg of defatted soy flakes (Unilever, Amsterdam, The Netherlands) were milled coarsely and suspended in 235 l of water. The pH was adjusted to 5.0, and Finase[®] S was added at a dosage of 1000 PU/g soy flakes. In the control test, no Finase[®] S enzyme was added. The suspension was incubated for 4 hours at 40° C with agitation. After the enzyme treatment, the pH was adjusted to 9.0 with NaOH flakes and the mixture was incubated for 1 hour without heating. After the alkaline extraction the mixture was cooled and the insoluble fraction was removed by drum filtration. Protein was precipitated by adjusting the pH to 4.5 with 30% H₃PO₄. The precipitate was recovered by separation and washed with water at pH 4.5. The separated protein fraction was freeze-dried.

The phytate content of the protein and the protein yield (dry weight basis) were determined. The results are shown in Table 2.

TABLE 2

Phytate Concentration and Protein Yield Achieved by Soy Protein Isolation According to the Invention on a Pilot Scale		
Finase dosage PU/g soy flakes	Phytic acid %	Protein yield %
0	1.8	22
1000	0.8	21

Table 1 shows that, using the process of the invention on a large scale, low-phytate soy protein isolate can be produced without a sacrifice in protein yield.

COMPARATIVE EXAMPLE 4

Reduction of Phytate content of Soy Protein Isolate

Ten g of commercial soy protein isolate (Purina Protein 1500, St. Louis, Missouri) were suspended in 100 ml of water. The pH was adjusted to 5.5, and Finase[®] S was added at dosages of 150, 500, 1000 PU/g protein. In the control test, no enzyme was added. Suspensions were incubated for 4 hours at 55° C.

After Finase treatment, the pH was adjusted to 4.5, and the proteins were recovered by centrifugation and freeze-dried. The phytate content of the protein isolate and the protein yields (dry weight basis) were determined. Results are shown in Table 3.

TABLE 3

Phytate Reduction and Protein Yield Achieved by Treatment of Soy Protein Isolate According to the Invention on a Laboratory Scale		
Finase dosage PU/g soy flakes	Phytic acid %	Protein yield %
0	1.8	89
150	1.1	88
500	0.0	86
1000	0.0	84

Table 3 shows that phytate-free soy protein isolates can also be produced by treating soy protein isolates with phytate-degrading enzymes after the protein isolation.

COMPARATIVE EXAMPLE 5

Reduction in Inositol Phosphate Achieved by Soy Protein Isolation According to the Invention

Twenty g of defatted soy flakes (Unilever, Amsterdam, The Netherlands) were milled coarsely and

suspended with 300 ml of water. The pH was adjusted to 9.0, and the suspension was incubated for 1 hour at room temperature. The insoluble fraction was removed by centrifugation.

The pH of the supernatant was adjusted to 5.0, and an amount of Finase[®] S was added to the slurry. Phytate-degrading activities are a major component of this enzyme preparation. The suspension was incubated for 4 hours at 55° C. In the control test, no enzyme treatment was conducted.

The enzyme dosages are presented as phytate degrading units/g flakes. One phytate-degrading unit (1 PU) is the amount of enzyme which liberates 1 nmol of inorganic phosphorous from sodium phytate per minute under standard conditions (40° C, pH 5.5).

The proteins were precipitated from the suspension by adjusting the pH to 4.5. The precipitate was recovered by centrifugation and freeze-dried. Protein yield and inositol phosphate contents of the protein fraction were determined.

The inositol hexa-, penta-, tetra- and triphosphates were determined according to the method of Sandberg et al., J. Food Sci. 54:159-162 (1989). Table 4 shows the contents of residual inositol phosphates of the proteins and the protein yields (dry weight basis).

TABLE 4

Inositol Phosphate Concentrations and Protein Yield Achieved by Soy Protein Isolation According to the Invention on a Laboratory Scale					
Finase dosage	Protein yield PU/g soy flakes	IP3 $\mu\text{mol/g}$	IP4 $\mu\text{mol/g}$	IP5 $\mu\text{mol/g}$	IP6 $\mu\text{mol/g}$
(%)					
28.2	0	0.00	1.97	2.58	11.39
26.1	500	0.00	0.00	0.00	0.00

Claims

1. A method of reducing or eliminating phytate in a composition comprising soy protein, the method comprising contacting a phytate-degrading enzyme with the composition at a pH of from 2.0 to 6.0 at a temperature of from 20°C to 60°C.
2. A method as claimed in claim 1 comprising:
 - a) adding an enzyme preparation of microbial origin comprising at least one phytate degrading enzyme to a particulate soy bean water slurry or a phytate containing soy protein isolate;
 - b) allowing phytate degradation to take place at a pH value of from 2.0 to 6.0, and at a temperature of from 20°C to 55°C; and
 - c) in the case of the slurry, isolating the resulting soy protein.
3. A method as claimed in claim 1 or 2, wherein the enzyme originates from Aspergillus spp., Rhizopus spp., or yeast.
4. A method as claimed in claim 1, 2 or 3 comprising:
 - a) suspending coarsely milled defatted soy particulate in an aqueous medium, to form a suspension;
 - b) adjusting the pH of the suspension to from 2.0 to 6.0, preferably from 4.5 to 5.5;
 - c) introducing into the suspension a phytase reducing amount of FINASE[®] S;
 - d) incubating the suspension for from 1.0 to 8.0 hours, at from 20°C to 50°C;
 - e) adjusting the pH of the suspension to about 9.0, and incubating the adjusted suspension for about 1 hour at room temperature;
 - f) separating an insoluble fraction from the suspension; and
 - g) separating the soluble soy protein from the suspension.
5. A method as claimed in claim 1, 2 or 3 comprising:
 - a) extracting protein from a defatted particulate soy bean aqueous suspension having a pH value of from 8.0 to 10.0;
 - b) removing any insoluble material from the suspension;
 - c) adjusting the pH of the suspension to from 2.0 to 6.0;

- d) introducing into the suspension a phytase reducing amount of FINASE[®] S;
 e) incubating the suspension for from 1.0 to 8.0 hours at from 20°C to 55°C;
 f) optionally adjusting the pH of the suspension of (e) to the isoelectric point of the protein to precipitate the protein and separating the precipitated protein to produce a precipitated protein and an aqueous solution.
- 5 6. A method as claimed in claim 1, 2 or 3 comprising:
 a) suspending an amount of commercial soy protein isolate in an aqueous medium, to form a suspension;
 b) adjusting the pH of the suspension to from 2.0 to 6.0;
 10 c) introducing into the suspension a phytase reducing amount of FINASE[®] S;
 d) incubating the suspension for from 1.0 to 8.0 hours, at a temperature of from 20°C to 65°C;
 e) adjusting the pH of the suspension to about 4.5; and
 f) separating the soy protein from the suspension thereby producing an essentially phytate-free soy protein isolate or concentrate, or a soy protein isolate having a reduced phytate concentration.
- 15 7. A method as claimed in claim 1, 2 or 3 comprising:
 a) extracting the protein from a defatted particulate soy bean aqueous suspension at a pH value of from 8.0 to 10.0;
 b) removing any insoluble material from the suspension;
 c) adjusting the pH of the suspension to the isoelectric point of the protein to produce a precipitated protein and an aqueous solution;
 20 d) separating the precipitated protein from the aqueous solution;
 e) redispersing the precipitated protein in an aqueous solution;
 f) adjusting the pH of the aqueous solution to from 2.0 to 6.0;
 g) introducing to the solution a phytase reducing amount of FINASE[®] S;
 25 h) incubating the solution for from 1.0 to 8.0 hours at from 20°C to 55°C;
 i) neutralizing the solution;
 j) spray-drying the solution.
8. A method as claimed in any of claims 1 to 7, wherein the concentration of enzyme, such as FINASE[®] S, is from 250 to 1000 PU/g soy particulate, preferably from 500 to 750 PU/g soy particulate.
- 30 9. A method as claimed in claim 1 having one or more of the following features:
 a) the composition is a soy protein isolate or soy protein concentrate;
 b) the temperature is from 40-55°C;
 c) the pH is from 4.5 to 5.5;
 d) the enzyme is added to the composition in the form of an enzyme preparation free of living matter.
 35 such as microorganisms;
 e) maintaining contact between the soy bean protein and enzyme for from 1.0 to 8.0 hours, preferably from 2 to 6 hours.
10. A soy protein isolate or concentrate prepared by the method as claimed in any of claims 1 to 9.

APPENDIX C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Deborah K. Ware
Group Art Unit: : 1651
Applicants : Wong et al.
Serial No. : 09/912,494
Filed : July 24, 2001
For : METHOD FOR PRODUCING ULTRAPURE PROTEIN
MATERIALS

Hon. Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION UNDER 37 CFR §1.132

Theodore M. Wong declares as follows:

1. I am an inventor of the subject matter of the above identified patent application.
2. I received a Bachelor of Arts Degree in Biology from Greensboro College in May, 1974, a Masters Degree in Microbiology from the University of Texas at Arlington in May 1976 and a Ph.D. Degree in Food Science/Food Biochemistry from Louisiana State University in May, 1982.
3. I have been employed by Solae, LLC, previously known as Protein Technologies International, Inc., since August 19, 1985, and currently hold the position of Senior Research Director, Product Development R&D.
4. Under my direction and control an experiment was conducted to determine the extent of degradation of phospho- and diphospho-ester nucleoside containing compounds in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS® phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample ("Control"), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solids ("Acid Phosphatase") and the third sample was dosed with NATUPHOS® phytase

enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids ("Natuphos"). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then treated with bacterial alkaline phosphatase to degrade monomeric nucleotides to monomeric nucleosides and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the amount of monomeric nucleotides and monomeric nucleosides present in the sample ("Monomerics"). Another sample of each of the three samples was treated with a nuclease to hydrolyze polymeric ribonucleic acids to monomeric nucleotides, then was treated with pyrophosphatase to hydrolyze ribonucleoside containing adducts to monomeric nucleotides, then was treated with bacterial alkaline phosphatase to hydrolyze the monomeric nucleotides to free monomeric nucleosides, and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the total amount of ribonucleoside containing compounds, both polymeric and monomeric, since the nuclease and pyrophosphatase treatments degrade the polymeric ribonucleoside-containing compounds to monomeric nucleotides, which are subsequently degraded to monomeric nucleosides with bacterial alkaline phosphatase ("Total"). The resulting ribonucleoside content by weight of nucleosides for each sample is shown in Table 1.

TABLE 1

Sample	Uridine	Cytidine	Guanosine	Adenosine	Total
Control					
--Monomerics	172	121	237	127	657
--Total	4302	5320	6711	5886	22219
Acid Phosphatase					
--Monomerics	5188	6886	7175	2204	21453
--Total	5281	7015	7599	2495	22390
Natuphos					
--Monomerics	231	128	240	184	783
--Total	4542	5628	6866	6070	23106

Table 1 shows that treatment with the acid phosphatase enzyme preparation produced a soy material product in which 95.8% $[(21453/22390)*100]$ of all ribonucleoside containing compounds were either in their monomeric nucleoside form or their monomeric nucleotide form—clearly indicating the degradation of most polymeric ribonucleic acids in the soy material. Table 1 also shows that treatment with the NATUPHOS[®] phytase enzyme produced a soy material product in which 3.3% $[(783/23106)*100]$ of all ribonucleoside containing products were either in their monomeric nucleoside form or their monomeric nucleotide form. The NATUPHOS[®] phytase enzyme degraded little or no polymeric ribonucleic acids, as can be shown by comparing amount of monomeric nucleosides and monomeric nucleotides in the soy material treated with NATUPHOS[®] to the Control, which contained 3.0% $[(657/22219)*100]$ of all ribonucleoside containing products as monomeric nucleosides or monomeric nucleotides. NATUPHOS[®], therefore, clearly did not degrade substantial amounts of ribonucleic acids to monomeric nucleosides or monomeric nucleotides, while the acid phosphatase enzyme preparation degraded almost all polymeric ribonucleoside-containing compounds to monomeric nucleosides and monomeric nucleotides.

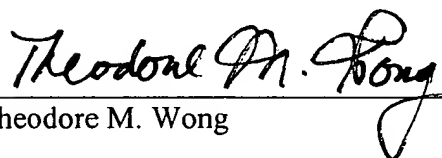
5. Under my direction and control an experiment was conducted to determine the extent of degradation of phytic acid in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS[®] phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample (“Control”), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solid (“Acid Phosphatase”) and the third sample was dosed with NATUPHOS[®] phytase enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids (“Natuphos”). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then analyzed to

determine phytic acid content, by weight percent of the soy protein material. The results are shown in Table 2.

TABLE 2

Sample	Phytic Acid (wt. %)
Control	1.46
Acid Phosphatase	0.12
Natuphos	0.11

Table 2 shows that both NATUPHOS[®] and the acid phosphatase enzyme preparation were effective to degrade phytic acid in a soy protein material relative to a soy protein material not treated with either enzyme. Tables 1 and 2, together, show that NATUPHOS[®] is effective to degrade phytic acid but not polymeric ribonucleoside-containing compounds such as ribonucleic acid, while an acid phosphatase enzyme preparation is effective to degrade both phytic acid and polymeric ribonucleoside-containing compounds such as ribonucleic acid.


Theodore M. Wong

Date: August 4, 2003



APPENDIX D



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Examiner : Deborah K. Ware
Group Art Unit: : 1651
Applicants : Wong et al.
Serial No. : 09/912,494
Filed : July 24, 2001
For : ULTRAPURE PROTEIN MATERIAL

Hon. Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

SECOND DECLARATION UNDER 37 CFR §1.132

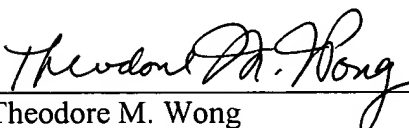
Theodore M. Wong declares as follows:

1. I am an inventor of the subject matter of the above identified patent application.
2. I received a Bachelor of Arts Degree in Biology from Greensboro College in May, 1974, a Masters Degree in Microbiology from the University of Texas at Arlington in May 1976 and a Ph.D. Degree in Food Science/Food Biochemistry from Louisiana State University in May, 1982.
3. I have been employed by Solae, LLC, previously known as Protein Technologies International, Inc., since August 19, 1985, and currently hold the position of Senior Research Director, Product Development R&D.
4. Under my direction and control an experiment was conducted to determine the extent of degradation of ribonucleic acid ("RNA") and phytic acid in a soy protein material by FINASE[®], a commercially available enzyme preparation containing acid phosphatase, at 38°C and at pH values of 4.5 and 5.1. Three samples of soy protein curd were prepared, a control sample having a pH of 4.5, a first test sample having a pH at 4.5 ("Sample 1") and a second test sample having pH at 5.1 ("Sample 2"). Sample 1 was dosed with a FINASE[®] enzyme preparation

containing acid phosphatase having an enzyme activity of 1400 PU ("Phytase Units") per gram curd solids, and Sample 2 was also dosed with a FINASE[®] enzyme preparation containing acid phosphatase having an enzyme activity of 1400 PU per gram curd solids. After dosing Sample 1 and Sample 2 with the enzyme preparations, Sample 1 and Sample 2 were heated to 38°C (100°F) for a period of two hours. Following the two hour reaction period, Sample 1 and Sample 2 were washed with water to remove degraded RNA and phytic acid. The ribonucleic acid content (in mg/kg) and the phytic acid content (weight %) were then measured in the Control and in Samples 1 and 2. The results are shown in Table 1 below.

	RNA Content (mg/kg)	Phytic acid content (%)
Control	14,700	1.5
Sample 1	1386	<0.07
Sample 2	6419	0.4

Table 1 shows that treatment of a soy protein material with a FINASE[®] enzyme preparation containing acid phosphatase does not necessarily result in a soy protein material containing at most 4000 mg/kg of RNA where the enzyme treatment is effective to produce a soy protein material having a low phytic acid content. Degradation of ribonucleic acids with the FINASE[®] enzyme preparation is less effective at low temperatures and at pH values above 5.0, where the combination of a low temperature and a pH above 5.0 reduces the RNA degrading efficacy of the FINASE[®] enzyme preparation such that the FINASE[®] enzyme preparation does not reduce the ribonucleic acid content in the soy protein material below 4000 mg/kg.


 Theodore M. Wong

Date: March 22, 2004

APPENDIX E

C.R. Ed Coco
SFV
CWK
GSL

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Total potentially available nucleosides of human milk by stage of lactation¹⁻⁴

James L Leach, Jeffrey H Baxter, Bruce E Molitor, Mary B Ramstack, and Marc L Masor

ABSTRACT Human milk-borne ribonucleotides reportedly have important physiological roles in breast-fed infants. Previous studies measured the free nucleotide content of human milk. To more fully evaluate the physiological capacity of nucleotides in human milk, we determined the monomeric and polymeric ribonucleotide and ribonucleoside content of milk pooled from 11 American women. Subsequently, we determined the total potentially available nucleosides (TPAN) of pooled and individual milk samples segregated by stage of lactation from 100 women in three European countries to test for effect of culture and diet. The methodology simulated *in vivo* digestion. Polymeric ribonucleotide (primarily RNA), monomeric ribonucleotide, and ribonucleoside-containing adducts (eg, uridine diphosphate hexose) were enzymatically hydrolyzed to their constituent ribonucleosides, the preferred form for absorption. Free and enzymatically liberated nucleosides were then measured by HPLC to yield the TPAN value. The mean (\pm SD) TPAN concentration of the 16 pooled European samples, derived from the 100 individual samples, was 189 ± 70 μ mol nucleoside/L human milk (range 82–402 μ mol/L). The means (μ mol/L human milk) of each nucleoside were 38 for uridine, 88 for cytidine, 31 for guanosine, and 32 for adenosine. These values included the contribution from the cellular portion of human milk. Only one of the 16 pooled samples contained a measurable amount of inosine (4 μ mol/L). The potentially available ribonucleosides in the human milk samples were predominantly present as monomeric ($36 \pm 10\%$) and polymeric ($48 \pm 8\%$) nucleotides. This study demonstrates that the traditional measurement of the free nucleotide content of human milk (which accounts for neither polymeric nor cellular nucleotides) underestimates the total nucleotides available to the infant by $\geq 50\%$. *Am J Clin Nutr* 1995;61:1224–30.

KEY WORDS Human milk, ribonucleic acid, nucleotide, nucleoside, ribonucleoside

INTRODUCTION

Nucleotides are ubiquitous, low-molecular-weight compounds consisting of a nitrogenous base (usually adenine, cytosine, guanine, thymine, or uracil), a sugar moiety (ribose or deoxyribose), and one to three phosphate groups (1). They are essential in energy metabolism and enzymatic reactions and are the monomeric units of polymeric RNA and DNA (1). As second messengers (cAMP, cGMP) and components of cofactors (NAD, NADP, FAD), nucleotides are an integral part of carbohydrate, lipid, protein, and nucleic acid metabolism (1, 2).

Nucleotide concentrations are maintained by *de novo* synthesis and by a salvage pathway that recovers metabolized nucleotides and nucleosides originating from the diet or intermediary metabolism (1, 3). The two pathways are regulated by dietary availability to maintain an adequate and continuous supply of tissue nucleotides (4–6). Polymeric forms of nucleotides (DNA and RNA) are generally the primary dietary source of nucleotides (3). Polymeric nucleotides are digested by phosphodiesterases (ribonucleases and deoxyribonucleases) to nucleotides (3), which are further degraded by phosphatases to nucleosides, the preferred form for absorption in the small intestine (3, 7).

When metabolic demand exceeds the capacity for *de novo* synthesis, for instance, during periods of rapid growth or after injury, dietary nucleosides and nucleotides may become conditionally essential nutrients. Tests of this hypothesis in animal models have focused on tissues undergoing high rates of cellular proliferation or rapid growth, particularly the developing gut and the responsive immune system. Dietary nucleosides were reported to be important in the growth and maturation of the developing gut and to play several roles in immune function (8, 9). These roles include availability to lymphocytes unable to synthesize nucleotides (10), immune stimulation in mice when added to nucleotide-free diets (11, 12), improved response to sepsis in mice (13, 14), enhanced lymphocyte proliferation (15), stimulation of immunoglobulin production in peripheral lymphocytes (16), and increased natural killer cell activity (17).

The presence of ribonucleotides in human milk has prompted clinical research into their potential benefit for developing infants and has led to speculation as to whether they should be added to infant formula (18). The effect of dietary nucleotides on infant growth was first reported in 1963 (19). Subsequently, nucleotide supplementation reportedly altered the profile of plasma lipids and lipoproteins (20–23) and the fecal microflora (24) of formula-fed infants to be more like those of breast-fed infants; some of these claimed effects were not corroborated in other studies (25, 26). In another report, lymphocytes from infants fed nucleotide-fortified formula showed increased

¹ From Abbott Laboratories, Ross Products Division, Columbus, OH.

² Participating physicians: Friedolf F Peters, Mainz, Germany; Eric Mallet, Rouen, France; A Henocq, Mount Saint Aignan, France; G Gios, Bolzano, Italy; and Ruggiero D'Elia, Treviso, Italy.

³ Address reprint requests to ML Masor, Abbott Laboratories, Ross Products Division, 625 Cleveland Avenue, Columbus, OH 43215.

Received September 7, 1994.

Accepted for publication February 13, 1995.

natural killer cell activity in an *in vitro* assay (27). Recently, nucleotide-fortified infant formula decreased the incidence of diarrhea in a group of infants of low socioeconomic status in Chile (28).

An accurate determination of the concentration and forms of ribonucleic acids in human milk is essential to evaluate their effect on outcomes of interest. Previous measurements have been nonspecific (29), or have measured only a portion of the total ribonucleic acid fraction (30, 31). Nonetheless, these data are the basis for the amount of ribonucleotide fortification in several commercial infant formulas. Because the entire polymeric ribonucleotide content of human milk has not been accurately measured, it has not been included as part of the nucleotide fortification of infant formula.

The method presented here measures all major sources of ribonucleotide in human milk potentially available for absorption and metabolism as ribonucleoside. It was first developed with a pooled, frozen sample of human milk from American women. Free nucleosides as well as those derived from nucleotides and nucleotide polymers were determined. Subsequently, several questions arose. Human milk is known to contain a significant number of cells; did the freezing and handling of the sample rupture these cells and release their nucleotide content? What was the contribution from nucleoside-containing adducts, such as uridine diphosphate glucose? Would the nucleotide concentration differ in the milk of women from other countries with diverse cultures and diets?

The present study was designed to answer these questions with an expanded sample size. Because all research on metabolically active nucleotides has been restricted to ribose-containing forms, deoxyribose forms were not considered. Henceforth, the terms nucleoside and nucleotide will refer only to ribose-containing forms.

SUBJECTS AND METHODS

For the initial method development, 11 lactating American women between 1 and 4 mo postpartum were brought to a collection center, where each completely emptied one breast under sterile conditions. These samples were immediately pooled, thoroughly mixed, divided into 10-mL aliquots, and frozen (-70°C) until analyzed. Details of the analysis are essentially the same as those of the present study described below, except that measurement of nucleotide-containing adducts was not included.

We attempted to distinguish between cellular and noncellular pools of nucleotides during the development of the method described below using the initial sample of human milk. The concentration of polymeric and monomeric nucleotide and free nucleoside was measured in a previously frozen, deactivated, pooled human milk sample as described below. The same sample was reanalyzed after cellular disruption by high-intensity sonification ($\pm 0.1\%$) (Triton X-100; Sigma, St Louis) before enzymatic hydrolysis. There was no significant increase in the concentration of polymeric and monomeric nucleotide and free nucleoside after the sonification procedure. Therefore, the measurement of the pooled and individual samples from the European human milk samples described below includes, and does not differentiate between, the cellular and noncellular pools of nucleic acids.

Subject selection

Human milk samples were collected from two sites in Italy, one in France and one in Germany. Sites were selected in these countries to address the question of the influence of differing diets and cultures on the total potentially available nucleosides (TPAN) of human milk. Subjects were selected from four stages of lactation: colostrum (through 2 d postpartum), transitional milk (3–10 d postpartum), early mature milk (1 mo postpartum), and late mature milk (3 mo postpartum). Five to seven individuals per site, per stage of lactation, contributed samples of human milk. A total of 100 individual samples were collected. Potential sample donors were contacted and the complete nature of the study described. If the potential donor expressed a willingness to participate in the study, written informed consent was obtained before collection of the sample.

Sample donors had no history of alcohol or drug abuse and had no medical condition or obstetrical complications thought to influence lactation. Donors had a singleton birth; had a hiatus of ≥ 15 mo since the cessation of breast-feeding an older child; had a preconceptional weight-for-height between 100% and 115% of ideal values; experienced adequate weight gain throughout pregnancy, as determined by the investigator and gave birth after a gestation of > 36 wk. Donors were not receiving any medication known to interfere with lactation and exclusively breast-fed their infant, i.e., the infant was fed ≤ 120 mL formula/d.

Sample collection

Milk was expressed at a collection center. The mother breast-fed the baby at midday on the same breast as the hand-dominance of the mother (i.e., right breast for right-handed mothers). When the baby was satisfied, the mother applied an electric breast pump to the nursed breast to ensure complete emptying. Any milk collected was discarded. About 60–90 min later, the mother washed the same breast with a mild soap and rinsed the breast repeatedly with distilled water. The breast pump was applied for ≈ 8 min to collect the sample while the baby suckled on the other breast to initiate let-down.

If a 50-mL sample could not be obtained in 8 min, the first sample was immediately frozen and a second 8-min sample was collected. Samples were collected into polyethylene containers labeled to indicate the donor's stage of lactation and stored at -75°C . The frozen samples were stored at the collection site until all of the samples from that site had been collected. Frozen samples were then shipped for analysis in dry ice to the laboratory via overnight express delivery.

Sample pooling and deactivation

Application of the complete analytical scheme (four hydrolyses in duplicate) on 100 samples would have required 800 separate analyses. Because of the length of the procedure, a decision was made to pool samples at each site. The acceptability of this decision was tested by comparing 20 individual samples from one site (five at each stage of lactation) to pools of those samples at each stage of lactation. Human milk contains enzymes that can degrade nucleic acids. Treatment of the milk with strong base inactivates most interfering enzymes but does not alter concentrations of TPAN. Samples were held at -75°C until analyzed. Samples from a single site were quickly thawed to room temperature, and aliquots of individual

samples at each stage of lactation were thoroughly mixed to provide a 20-mL sample of pooled milk. Sodium hydroxide (1 mol/L) was added (40 mL) and the samples were covered and stirred for 30–60 min. The pH of the samples was then adjusted to 7.0–7.5 with hydrochloric acid, and diluted to 100 mL with water. Five-milliliter aliquots of individual samples from one site were similarly treated (by using 10 mL sodium hydroxide and brought to 25 mL with water).

Enzymatic hydrolyses

Four distinct sample preparations were carried out in duplicate with 5 mL deactivated, diluted sample, stirred in a Pierce heating-stirring module (Reacti-Therm; Rockford, IL). An internal standard, 5-methylcytidine (30 µg; Sigma #M-6254) was added to every sample preparation. Figure 1 depicts the action of the three enzymes used in these preparations. In preparation 1, duplicate deactivated human milk samples were incubated 16–18 h with nuclease (nuclease P1 phosphodiesterase, 19 U; Sigma #N-8630) to hydrolyze polymeric to monomeric nucleotide by using a modification of the procedure described by Gehrke and Kuo (32). This was followed by incubation with pyrophosphatase (nucleotide pyrophosphatase, 0.4 U; Sigma #P-7383) to release nucleotide from adducts, and with phosphatase (bacterial alkaline phosphatase, 16 U; Sigma #P-4252) to hydrolyze nucleotide to nucleoside by using the modified procedure of Gehrke and Kuo (32) for 3 h at 37 °C. Preparation 2 included both the nuclease and phosphatase hydrolysis, preparation 3 used the phosphatase hydrolysis only, and preparation 4

was the unhydrolyzed deactivated sample. Samples were then quantitatively transferred to 25-mL volumetric flasks with 12.5 mL 0.5 mol potassium phosphate/L, pH 10.5, and brought to the desired volume with water.

Solid-phase extraction

The procedure described here is based on the work of Uziel et al (33). The solid-phase extraction media was Affi-Gel 601 (#153-6101; Bio-Rad, Melville, NY). Hydrated, settled gel (150 µL) in a polypropylene microcentrifuge tube was washed twice with buffer (250 mmol potassium phosphate/L, pH 10.5) by vortexing, followed by centrifugation and removal of supernate. The washing procedure converted the gel to the basic form. A 1-mL aliquot sample from the enzymatic preparations described above was added to the gel and vortexed, binding the nucleosides to the gel. Contaminating compounds were removed from the gel-bound nucleosides by two 1-mL washings with the potassium phosphate buffer. Nucleosides were then eluted from the gel by using 750 µL 1 mol phosphoric acid/L and passed through a 0.22-µm filter directly into a vial for HPLC analysis.

HPLC analysis

The nucleosides were separated via reversed-phase, pairing chromatography on an octadecylsilane stationary column (#4M, 5314; Jones Chromatography, Lakewood, CO). The mobile phase was 100 mmol potassium acetate/L, pH 10.5, and 2 mmol hexane sulfonic acid/L (Sigma #H9026) organic modifier was acetonitrile, with an initial concentration of 1%, which was linearly increased to 7% from 0 to 8 min, held at 7% for 2 min, and reequilibrated at 1% for 8 min before the next injection. The nucleosides were detected by fluorescence at 255 nm. Calibration curves for each nucleoside were constructed by calculating the ratios of the area response of known concentrations of serially diluted nucleoside standards (Sigma products: U-3750, C-9505, I-4125, G-4125, and A-9251) to the area of a fixed concentration of the internal standard 5-methylcytidine. Linear regression gave correlation coefficients > 0.9995. The sample concentration of each nucleoside was calculated by using the linear regression for nucleoside and the area ratio (nucleoside-internal standard) from analyses.

Data reduction and precision

The nucleoside concentrations measured after the four distinct sample preparations permitted determination of the amount of each nucleoside found in each form and the amount each form contributed to TPAN.

Preparation 1: Measurement of inherent free nucleosides and nucleosides resulting from nuclease, pyrophosphatase, and phosphatase hydrolysis gave the TPAN value.

Preparation 2: Hydrolysis with nuclease and phosphatase gave the amount of inherent, nucleotide-derived, and polymer-derived nucleosides. Preparation 1 – preparation 2 = nucleosides derived from nucleoside-containing adducts.

Preparation 3: Hydrolysis with phosphatase provided inherent and nucleotide-derived nucleosides. Preparation 2 – preparation 3 = polymer-derived nucleoside.

Preparation 4: No enzymatic hydrolysis yielded inherent nucleosides. Preparation 3 – preparation 4 = nucleotide-derived nucleoside.

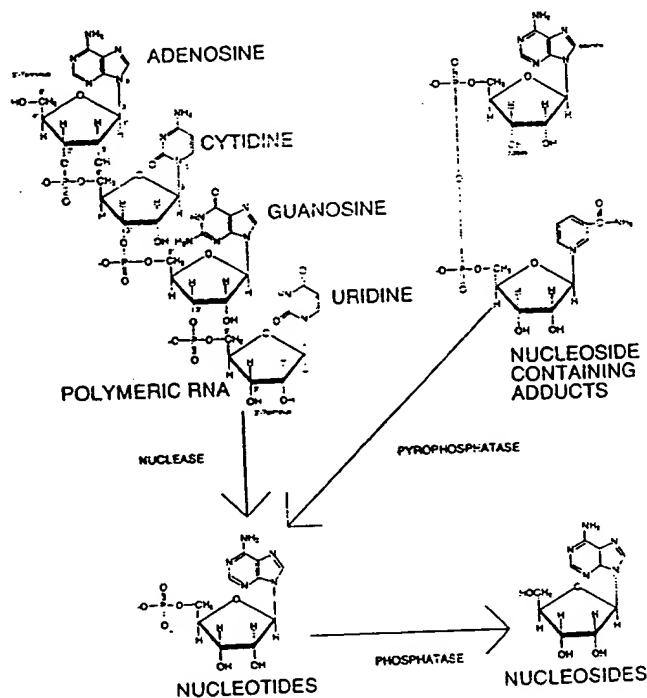


FIGURE 1. The enzymatic digestion of ribonucleotide. Polymeric RNA, and nucleoside-containing adducts (nucleoside-phosphate-phosphate-X, where X is any of a group of biologically relevant moieties, eg. NAD, UDP-glucose) are hydrolyzed to their corresponding nucleotides by the actions of nucleases and pyrophosphatases, respectively. Ribonucleotide is further hydrolyzed to nucleoside, the preferred form for absorption in the gut, by the action of phosphatases.

Preliminary computations demonstrated that the SD was proportional to the mean. Therefore, the percent relative SD (% RSD) for each duplicate was a more appropriate estimate of the variability of the measurement than the SD.

Overfortification recoveries

An aqueous TPAN-fortified solution was prepared that contained ribonucleosides, 5'-mononucleotides, polymeric yeast RNA, and nucleoside-containing adducts (uridine diphosphate glucose, cytidine diphosphate choline, guanosine diphosphate mannose, and NAD), all at concentrations 100 times those typical for human milk. An aliquot was diluted 1:100 with water and hydrolyzed for 16 h in 0.2 mol potassium hydroxide/L to quantitatively cleave all of the polymeric RNA to 2'- and 3'-mononucleotides. The pH of this solution was adjusted to ≈ 9 with hydrochloric acid and incubated with alkaline phosphatase and nucleotide pyrophosphatase to hydrolyze all nucleotide and nucleoside-containing adducts to nucleoside, and the nucleoside concentrations were measured directly (without solid-phase extraction). Because previous work (data not shown) demonstrated that the phosphatase- and pyrophosphatase-catalyzed reactions were quantitative, this alkaline and enzymatic hydrolysis and HPLC analysis was used to define theoretical concentrations. The TPAN-fortified solution was diluted 1:100 with one of the pooled human milk samples (early mature milk from site 3, Italy) and the TPAN analysis carried out to determine recovery.

RESULTS

When the difference between the fortified and unfortified pooled sample is compared with the concentration derived from the alkaline enzymatic hydrolysis of the fortified solution, 91% of the theoretical TPAN value was recovered (Table 1). The method recovered within 5% of the "actual" value for cytidine and adenosine and underestimated the uridine value by $\approx 12\%$ and the guanosine value by $\approx 24\%$. The %RSD of the

TABLE 1
Accuracy and precision of the total potentially available nucleosides (TPAN) method

Test samples	Uridine	Cytidine	Guanosine	Adenosine	TPAN
TPAN-fortified ($\mu\text{mol/L}$) ¹	64	70	73	69	276
Pooled milk ($\mu\text{mol/L}$)	67	146	91	97	402
Pooled milk + TPAN-fortified ($\mu\text{mol/L}$)	124	219	147	165	654
Difference ($\mu\text{mol/L}$)	57	73	55	67	252
Percent recovery (%) ²	88	104	76	98	91
Precision of TPAN method					
Relative standard deviation (%RSD) ³	3.6	2.0	2.0	2.0	1.9

¹ An aqueous solution of nucleosides, monomeric and polymeric nucleotides, and nucleoside-containing adducts at concentrations found in human milk, and subjected to alkaline and enzymatic hydrolysis to yield theoretically accurate concentrations.

² Difference between the fortified and unfortified pooled milk sample divided by the concentrations measured in the TPAN-fortified solution.

³ Computed from 16 degree-of-freedom estimate of the variance.

measurement of each of the four nucleosides and the TPAN value is an indicator of the precision of the measurement (Table 1). The variance of the method makes only a very small contribution to the between-sample variance in this study.

Table 2 provides a summary of all TPAN data by site and by stage of lactation. Comparison between sites at each stage of lactation shows considerable variability. The mean ranges of TPAN values ($\mu\text{mol/L}$) from the different sites were 82–164 (colostrum), 144–210 (transitional milk), 172–402 (early mature milk), and 156–259 (late mature milk). Comparison between stages of lactation at each site shows equal variability in TPAN ($\mu\text{mol/L}$): 146–172 at site 1, 82–219 at site 2, 164–214 at site 3, and 150–402 at site 4. The mean TPAN (sites combined) was lowest in colostrum (137 $\mu\text{mol/L}$) but showed no consistent upward or downward trend in transitional milk (177 $\mu\text{mol/L}$), early mature milk (240 $\mu\text{mol/L}$), or late mature milk (202 $\mu\text{mol/L}$). Also shown in Table 2, the mean TPAN (excluding adducts) from pooled American milk (161 $\mu\text{mol/L}$) was within the range of the European milk (82–402 $\mu\text{mol/L}$).

The percentage of each form of the mean TPAN for the entire European pool is provided in Table 3. Most of the TPAN was present as polymeric ($48 \pm 8\%$; $\bar{x} \pm \text{SD}$) and monomeric

TABLE 2
Nucleotide and total potentially available nucleoside (TPAN) in pooled human milk by stage of lactation¹

	Uridine	Cytidine	Guanosine	Adenosine	TPAN
	$\mu\text{mol/L}$				
Colostrum					
Site 1	27	84	22	20	153
Site 2	21	33	15	13	82
Site 3	30	82	26	26	164
Site 4	24	84	20	22	150
Mean	26	71	21	21	137
Transitional milk					
Site 1	23	82	23	19	146
Site 2	33	76	19	17	144
Site 3	37	84	43	42	206
Site 4	36	100	36	38	210
Mean	32	86	30	29	177
Early mature milk					
Site 1	30	86	28	28	172
Site 2	50	79	23	21	173
Site 3	44	96	36	37	214
Site 4	67	146	91	97	402
Mean	48	102	45	46	240
Late mature milk					
Site 1	36	73	22	25	156
Site 2	58	106	29	27	219
Site 3	49	81	20	24	173
Site 4	45	124	40	49	259
Mean	47	96	28	31	202
Grand Mean	38	88	31	32	189
SD	13	24	18	20	70
Range	21–67	33–146	19–92	13–97	82–402
American pool ²	37	70	30	24	161

¹ The data are from 100 individual samples collected at four sites and combined into 16 pooled samples (5–7 individual samples per site per stage of lactation). Site 1, Rouen and Mount Saint Aignan, France; Site 2, Mainz, Germany; Site 3, Bolzano, Italy; Site 4, Treviso, Italy.

² A pooled sample of milk collected from 11 American women between 2 and 4 mo postpartum.

TABLE 3

Percentage of total potentially available nucleosides (TPAN) in pooled human milk as adducts, polymeric nucleotides, monomeric nucleotides, and nucleosides¹

	Uridine	Cytidine	Guanosine	Adenosine	TPAN
	% of total				
Polymeric nucleotides	19 ± 7	57 ± 12	59 ± 21	47 ± 11	48 ± 8
Monomeric nucleotides	36 ± 12	37 ± 13	34 ± 14	35 ± 10	36 ± 10
Nucleosides	18 ± 14	5 ± 5	1 ± 2	5 ± 4	8 ± 6
Adducts ²	27 ± 12	1 ± 1	7 ± 15	13 ± 9	9 ± 4

¹ $\bar{x} \pm$ SD. Based on the mean of the entire pool of human milk collected from 100 individuals at four stages of lactation at four sites.

² Adducts are of the form nucleoside-phosphate-phosphate-X, where X is a biologically relevant moiety, for example, uridine diphosphate galactose or NAD.

(36 ± 10%) nucleotide. Nucleosides (8 ± 6%) and nucleotide from adducts (9 ± 4%) were a small but significant contribution. Monomeric and polymeric nucleotides were also the predominant forms of TPAN in the pooled sample of American milk (data not shown) accounting for 93% of the total (excluding adducts).

The distribution of individual nucleotides in each fraction is also shown in Table 3. Uridine was found in all fractions, but primarily as free nucleotide (36 ± 12%) and adduct (27 ± 12%). Cytidine, guanosine, and adenosine were mostly in the polymeric and monomeric nucleotide fractions.

To demonstrate the acceptability of the decision to pool samples, comparisons were made between pooled sample values to the mean values of the five individuals contributing to those pools at site 3 (Italy). The concentrations of individual nucleosides and the TPAN values of the pooled samples and the means of the individuals in the pools at each stage of lactation are given in Table 4. At every stage of lactation, both for individual nucleosides and for TPAN, the measured value of the pooled sample is virtually identical to the mean of the five individual samples that formed that pool.

TABLE 4

The total potentially available nucleosides (TPAN) of pooled samples compared with individual human milk samples¹

	Uridine	Cytidine	Guanosine	Adenosine	TPAN
	μmol/L				
Pooled colostrum sample mean	30	82	26	26	164
Mean of samples in pool (n = 5)	29	81	27	27	169
Range of individual samples	17-39	23-144	11-51	17-46	83-253
Pooled transitional milk mean	37	84	43	42	206
Mean of samples in pool (n = 5)	35	85	43	42	214
Range of individual samples	16-61	43-123	10-91	17-86	88-378
Pooled early mature milk mean	44	96	36	37	214
Mean of samples in pool (n = 5)	44	92	35	37	215
Range of individual samples	23-61	61-129	18-80	20-77	126-357
Pooled late mature milk mean	49	81	20	24	173
Mean of samples in pool (n = 5)	47	79	19	23	171
Range of individual samples	23-113	50-108	5-41	6-54	90-325

¹ Pooled samples consisted of individual samples from 20 women (5 per stage of lactation).

MJ. Leach 185 24.5 34 45.2 31 14.1 18.7
 MJ. Enfamil sample 34 11 4 5

DISCUSSION

The recovery of adenosine and cytidine from human milk samples (Table 1) appeared to be accurate within 5%. Although the measurement of uridine and guanosine was less accurate, all analyses had high precision. Previous work in this laboratory indicated that the underestimation of guanosine, and probably of uridine, is the result of incomplete elution of these nucleosides from the solid-phase extraction media (boronate derivitized gel). Incomplete enzymatic liberation of the guanosine residues or a contaminating degradative activity that acts on guanosine could also contribute to its underestimation. The TPAN method recovers between 90% and 95% of the true TPAN value, while slightly underestimating the uridine content, and significantly underestimating the guanosine content.

This study answered the questions raised by the preliminary work, and confirmed and extended those data. The failure to detect any increase in TPAN in human milk after cellular disruption by high-intensity sonication indicates that the nucleotide content of the cells present in human milk was accounted for in the TPAN analysis. The procedure by which milk samples were collected, frozen, thawed, and deactivated with strong base apparently resulted in complete release of nucleotides before the analysis.

The addition of nucleotide pyrophosphatase treatment to TPAN analysis permitted estimation of the nucleotides from nucleotide-containing adducts. Overall this represents ± 4% of the TPAN value (Table 3), a small but significant addition, because the adducts accounted for a good portion of the human milk uridine (27 ± 12%). The work of Rual (10), Van Buren et al (12), Kulkarni et al (13), and I et al (14) suggests that uridine may account for much of the immunological effects attributed to nucleotides.

Most importantly, these data show a wide range of concentrations of four individual nucleosides as well as the TPAN of these 16 pooled samples, representing 100 individual human milk samples. Ranges for the entire pool (Table 4) are 21-67 μmol uridine/L, 33-146 μmol cytidine/L, 19-51 μmol guanosine/L, and 13-97 μmol adenosine/L, for an average of 82-402 μmol TPAN/L. Cytidine was consistently the nucleotide in greatest concentration (88 ± 24 μmol/L).

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uridine was consistently found in greatest concentrations as adduct ($27 \pm 12\%$) and free nucleoside ($18 \pm 14\%$). In the comparison between pooled and individual samples from site 3 (Italy), there was excellent agreement between the mean concentrations of the individual samples and the concentration of the pooled sample to which they contributed. However, there was a wide range of values among the samples at all sites over the course of lactation and at any given stage of lactation.

In answer to our third question, this sample-to-sample variability appears to be a property of human milk and not a function of the measurement or stage of lactation. If one assumes that diet varies with nationality, maternal diet also was not a factor. The collection method was well standardized and should not have been a source of variability. Concentrations in colostrum were somewhat lower than the other types of milk, and purine concentrations were generally lower and varied more than the pyrimidine concentrations. However, there was no consistent relation between TPAN concentration, stage of lactation, or country in which the women resided for the European milk samples. The concentration of polymeric and monomeric nucleotides and nucleosides, and the relative proportions of individual nucleosides in the pooled sample of milk from American women were similar to the values in samples of milk from European women (Table 2).

Although there was variability in TPAN among the pooled samples, the percentage of the total contributed by each form was more constant. The nucleotides in these samples were predominantly present as monomeric and polymeric nucleotides. The sum of these two forms ranged from 72% to 92% of the total in the 16 pooled samples with an average of 84%. Consistently, only low concentrations of nucleosides were present, with uridine predominating. Slightly higher concentrations of nucleoside-containing adducts were also present, again with uridine derivatives predominant. Similar relations between the amounts of RNA, nucleotide, and nucleoside were found in the pooled sample of milk from American women (data not shown).

Earlier reports of the nucleotide content of human milk have either described only the monomeric portion or total RNA. Furthermore, previous measurements of RNA in human milk have been less specific or comprehensive. Typical of the non-specific measurements was a report by Sanguanserm Sri et al (29) of RNA concentrations in human milk of ≈ 300 – $1800 \mu\text{mol/L}$. The method of analysis did not involve selective isolation of the nucleic acid fraction before measurement. In addition, the actual measurement procedure was nonspecific and prone to overestimation in complex sample matrixes. More specific and accurate measurements of some forms of ribonucleic acids have been reported. Janas and Picciano (30) measured via HPLC the concentration of mono- and diphosphate nucleotides in human milk during 3 mo of lactation. Gil and Sanchez-Medina (31) reported concentrations for mononucleotides and included many nucleoside-containing adducts (eg, uridine diphosphate hexose and guanosine diphosphate mannose). Neither of these studies of specific forms of nucleotides provided an assessment of the total concentration presumably available in vivo on digestion.

Our data agree well with the previous reports of specific components of the monomeric nucleotide fraction of human milk. When the mean of the 16 pooled samples and the average percentages as nucleotide are used, there are $14 \mu\text{mol}$ uridine

nucleotide/L, $33 \mu\text{mol}$ cytidine nucleotide/L, $10 \mu\text{mol}$ guanosine nucleotide/L, and $11 \mu\text{mol}$ adenosine nucleotide/L for an average total of $68 \mu\text{mol}$ nucleotides/L and a range of 39 – $161 \mu\text{mol}$ nucleotides/L. This measurement does not distinguish between and includes contribution from mono-, di-, and triphosphonucleotides. Janas and Picciano (30) measured mono- and diphosphonucleotide concentrations and reported mean values of $10 \mu\text{mol}$ uridine nucleotide/L, $27 \mu\text{mol}$ cytidine nucleotide/L, $6 \mu\text{mol}$ guanosine nucleotide/L, and $7 \mu\text{mol}$ adenosine nucleotide/L, for a total of $56 \mu\text{mol}$ nucleotide/L (including inosine monophosphate).

Janas and Picciano (30) measured inosine monophosphate at various stages of lactation, and the range of their reported values was 1.5 – $18.4 \mu\text{mol/L}$ with an average of $6.5 \mu\text{mol/L}$. In the present study, inosine derivatives could only be found in 1 of the 16 pooled samples ($4 \mu\text{mol/L}$ in a sample containing $402 \mu\text{mol}$ TPAN/L) and detected at trace concentrations ($> 1 \mu\text{mol}$ inosine derivative/L milk) in eight others. But 7 of the 16 pooled samples did not contain detectable inosine concentrations. Previous results (data not shown) indicated that human milk contains adenosine deaminase activity (ADA) and that adenosine added to a human milk sample in which ADA had not been deactivated could be partially recovered as inosine. We therefore believe that the presence of inosine in an analysis of human milk may be a sample-preparation artifact. In that regard, the highest concentration of inosine that could be measured represented only 1% of the total of that sample.

Gil and Sanchez-Medina (31) also measured individual nucleotide concentrations, which agree well with this study's determination. In addition, they measured guanosine diphosphate mannose concentrations and found $\approx 5 \mu\text{mol/L}$ at various stages of lactation. The average result for adduct-derived guanosine in the present study was $\approx 2 \mu\text{mol/L}$ and ranged from not detectable to $\approx 11 \mu\text{mol}$ adduct-derived guanosine/L. Gil and Sanchez-Medina (31) also measured uridine diphosphate hexosamine plus uridine diphosphate hexose concentrations, which ranged from ≈ 5 to $> 30 \mu\text{mol/L}$. In the present study $\approx 10 \mu\text{mol}$ uridine adduct/L was measured, with a range from < 1 to $\approx 21 \mu\text{mol}$ uridine adduct/L.

There is continued interest among clinical researchers in the field of infant nutrition and some regulatory agencies to accurately determine the amount of ribonucleotides in human milk for use in infant formula. The in vitro enzymatic digestion of the method described here approximates in vivo digestion (Figure 1). Monomeric nucleotides were obtained by the digestion of RNA and nucleoside-containing adducts (a nucleoside-containing adduct is of the general formula nucleoside-phosphate-phosphate-X, where X is any of a group of biologically relevant moieties). Liberated and inherent mononucleotides were further digested to nucleosides, the preferred form for absorption in the gut (3, 7). The subsequent extraction with a boronate derivitized support and separation via HPLC allowed accurate measurement of isolated uridine, cytidine, inosine, guanosine, and adenosine. Measurement of the inherent free nucleosides followed by sequential application of the three enzymatic hydrolyses allowed estimation of the TPAN as polymeric nucleoside (RNA), nucleotide, nucleoside, and nucleoside-containing adduct, and the percentage of each nucleoside present. This complete enzymatic hydrolysis and measurement of the entire nucleotide fraction of human milk is a reasonably accurate reflection of the in vivo process: ie, TPAN.

These data suggest that if there is a need for the addition of nucleotides to infant formula, substantially larger amounts than are currently used would be required to achieve the average TPAN concentration in human milk.

We give special thanks to Vickie Pound and Norman White for their exceptional dedication, diligence, and the high quality of their work in the performance of this study.

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APPENDIX F



US006313328B1

(12) **United States Patent**
Ulrich et al.

(10) Patent No.: **US 6,313,328 B1**
(45) Date of Patent: ***Nov. 6, 2001**

(54) **EXTRACTION OF CORN OIL FROM
FLAKED CORN GRAIN**

(75) Inventors: **James F. Ulrich, Plymouth; Stephan
C. Anderson, deceased, late of
Minneapolis, both of MN (US), by Beth
R. Anderson, legal representative**

(73) Assignee: **Cargill, Incorporated, Wayzata, MN
(US)**

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/249,280**

(22) Filed: **Feb. 11, 1999**

(51) Int. Cl.⁷ **C07C 1/00**

(52) U.S. Cl. **554/13; 554/9; 554/12;
554/20; 554/21; 426/417**

(58) Field of Search **554/9, 12, 13,
554/20, 21; 426/417**

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Primary Examiner—Deborah D. Carr

(74) Attorney, Agent, or Firm—Fish & Richardson P.C., P.A.

(57) **ABSTRACT**

A commercial-scale method for processing corn grain includes the steps of flaking corn grain having a total oil content of at least about 8% and extracting a corn oil from the flaked corn grain. Such a method can be effectuated by processing the high oil corn grain using methods and equipment typically used to process soybeans and other similar oilseed types. In this way, processing plants that flake oilseeds can be used to extract corn oil from corn.

23 Claims, No Drawings

EXTRACTION OF CORN OIL FROM FLAKED CORN GRAIN

FIELD OF THE INVENTION

The invention relates to processing corn. In particular, the invention relates to processing corn to produce a corn oil and/or a meal product.

BACKGROUND OF THE INVENTION

Corn, *Zea mays* L., is grown for many reasons including its use in food and industrial applications. Corn oil is one of many useful products derived from corn. Commercial processing plants utilizing conventional methods for extracting corn oil typically separate the corn seed into its component parts, e.g., endosperm, germ, tipcap, and pericarp, and then extract corn oil from the corn germ fraction.

Although the precise processing steps and types of equipment vary somewhat from plant to plant, commercial corn processing can be classified as either a wet milling or dry milling process. Overall, wet milling is a sophisticated process involving many steps. When isolating the corn oil fraction, corn seed is first steeped in a water/sulfur dioxide (SO₂) mixture at an elevated temperature and then passed through degerminating mills to separate out the corn germ. The wet milled germ contains about 50% oil, which is then washed and dried.

Dry milling physically separates the germ and pericarp from the rest of the corn seed. Dry milling can include tempering the seed by adding water followed by drying, cooling, grinding, sifting and aspirating the seed. Degermination is accomplished using a Beall degerminator (™), impact mills, granulators or other similar degerminating equipment. The oil content of dry milled germ ranges from about 18% to about 27% oil.

Corn oil is extracted from wet milled or dry milled germ using physical expellers, solvent extractors, or a combination of both. Wet milled germ typically undergoes a two-step extraction because complete oil extraction is often unattainable using a single extraction.

It is also conventional practice to condition corn germ before oil extraction by adding moisture and heating the germ to about 100° C. Conditioning facilitates complete oil extraction. Heating corn seed or germ before or during the extraction, however, can detrimentally affect oil quality.

Corn oil extracted using wet milling methods has a dark color and requires additional processing to achieve a useful oil. Dry milling methods tend to produce a better quality oil. Nevertheless, both dry and wet milling processes have drawbacks that include high energy costs, expensive equipment, high maintenance costs, and variable oil quality. Other corn oil recovery methods have been attempted, but most have not proven to be commercially feasible. Thus, there exists a need for improved methods that alleviate one or more of the drawbacks associated with conventional corn oil recovery methods.

SUMMARY OF THE INVENTION

In one aspect, the invention features a commercial-scale method for processing corn grain that includes the steps of flaking corn grain, and extracting an oil from the flaked corn grain. The corn grain should have an elevated total oil content of at least about 8%. The corn processing method may be effective for producing corn oil and corn meals having defined characteristics.

In one embodiment, the corn grain has a total oil content of at least about 14%. In alternative embodiments, the corn

grain has a total oil content of at least about 12%, at least about 10%, or from about 12% to about 30%.

In another embodiment, the corn grain being flaked is whole corn grain. In another embodiment, the corn grain is cracked corn grain.

In another embodiment, the method of processing corn includes an extracting step wherein the flaked corn grain is pressed to extract an oil. Alternatively, the extraction step exposes the flaked corn grain to solvent-based oil extraction. Solvents used to extract miscible or soluble substances from the flaked grain include hexane, n-hexane, isopropyl alcohol, and supercritical carbon dioxide. Extracting steps can produce a miscella and a corn meal.

In another embodiment, the corn meal resulting from corn processing has a fiber content of about 3%, a starch content of about 65%, and a protein content of about 14%, at a moisture content of about 10%. In alternative embodiments, a subset of the fiber content, starch content, and protein content are measured in the resulting meal. For example, a corn meal may have a fiber content of about 3%, and a protein content of about 14%, at a moisture content of about 10%.

In another embodiment, miscella is desolventized to produce a corn oil. The corn oil may be further refined. The corn oil may have a phosphorous content of less than about 500 parts per million, a free fatty acid content of less than about 0.3%, and/or a neutral oil loss of less than about 2%.

In another embodiment, the corn oil has a light yellow color. The color of the corn oil may have yellow and red colors. The yellow color values may range from about 60 to about 70 and red color values may range from about 7 to about 10, as determined by American Oil and Chemical Society method Cc 13b-93.

In another embodiment, the corn processing method is effective for processing at least about 100 tons of corn per day or for processing from about 100 tons of corn per day to about 3,000 tons of corn per day.

In another aspect, the invention features a method of selling corn seed that includes the offering corn seed for sale, or actually selling corn seed, wherein the corn seed can produce corn grain having a total oil content of at least about 8% and advertising that the corn grain may be processed by flaking the corn grain. In one embodiment, the method includes advertising that the flaking of the corn grain is effective for producing a corn oil.

In another aspect, the invention features a method for marketing corn seed that includes making, using, selling offering for sale, or otherwise providing corn seed wherein the corn seed can produce corn grain having a total oil content of at least about 8% and advertising that the corn grain may be processed by flaking the corn grain. In one embodiment, the method includes advertising that the flaking of the corn grain is effective for producing a corn oil.

In another aspect, a novel method of doing business comprises the steps of buying, purchasing, or offering to buy corn grain having a high oil content for the purpose of processing the purchased grain by flaking the grain and extracting an oil therefrom. In one embodiment, the method includes advertising that a facility flakes high oil corn grain.

In another aspect, the invention features an article of manufacture that includes packaging material, a label accompanying the packaging material and seed corn contained within the packaging material. The packaged seed corn is effective for producing grain having a total oil content of at least about 8%. Labels associated with the

article of manufacture indicate that the grain produced by the ~~method can be processed by flaking the grain and extracting an oil therefrom.~~

Advantages of the invention include commercially feasible methods for extracting an oil from corn without having to steep the corn or heat the corn to elevated temperatures. Corn oil can be extracted from whole corn grain without having to separate the corn grain into its component parts. The corn oil produced can be of a better quality than the oil produced by known wet-milling methods, which currently process about 50,000,000 tons of corn grain per year world wide. Dry milling, on the other hand, accounts for about 3,000,000 tons of corn grain per year. The crude oil can require fewer processing steps. Oil loss during the oil processing can be minimized. Products other than corn oil can still be obtained ~~using equipment used for other seed types, such as soybeans, can be utilized for multiple grains.~~

Unless otherwise defined, all technical and scientific terms and abbreviations used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. All patents, publications and official analytical methods referred to herein are incorporated by reference in their entirety. Additional features and advantages of the invention will be apparent from the following description of illustrative embodiments of the invention and from the claims.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

It has been discovered that corn oil can be rapidly and efficiently extracted on a commercial-scale from corn grain having increased oil content by flaking the corn grain and extracting a corn oil. Useful corn grain for the novel flaking oil processing method has a total oil content greater than about 8%. Increases in the oil content of corn grain may increase flaking efficiency during processing. Suitable flaking equipment and methods include conventional flaking equipment and methods used for flaking soybean and other similar oilseed types. Suitable extracting equipment and methods may include conventional methods used for extracting oil from soybean flakes and other similar oilseed types.

~~The invention can be used for seeds or grain other than corn, such as soybeans, sunflowers, rapeseed, and canola, exclude some of the conventional corn oil processing steps. For example, preprocessing of soybeans for oil extraction includes drying, cracking, and aspirating the soybeans to separate the meats from the seed hulls. The meats are then pushed into thin flakes by passing the meats through flaking rollers without removing the germ or embryo. Oil is then extracted from the flaked meats using physical or chemical extraction methods.~~

Corn seed or "grain" harvested from many types of corn plants are useful in the invention. Such corn plants may be hybrids, inbreds, or a population. Useful grain types include, for example, flint corn, popcorn, flour corn, dent corn, white corn, and sweet corn. The grain can be in any form including whole corn, cracked corn, or other processed corn or parts thereof that are amenable to flaking.

Commercial-scale methods and equipment are sufficient for extracting corn oil from at least about 100 tons of corn per day. In some embodiments, the capacity of commercial-

scale operations ranges from about 100 tons of corn per day to about 3000 tons of corn per day, or the capacity ranges from about 700 tons of corn per day to about 1700 tons of corn per day. Commercial-scale operations that process greater than about 3000 tons of corn per day are also sufficient.

Useful corn grain has a total oil content greater than about 8%, which is greater than the total oil content of current commodity grade number 2 yellow dent corn, which has an oil content of about 3% to about 5%. Additionally, the total oil content of corn grain suitable for the invention can be, for example, grain having an oil content of at least about 9%, at least about 11%, at least about 12%, at least about 14%, at least about 18%, at least about 20%, from about 8% to about 20% oil, from about 10% to about 30% oil, or from about 14% to about 30%, and values therebetween. Although the oil content can be determined at any moisture content, it is acceptable to normalize the oil content to a moisture content of about 15.5%.

Corn grain having an increased total oil content can be identified and obtained using any method. For example, corn ears can be selected using a near infrared (NIR) oil detector to select corn ears having corn kernels with elevated oil levels or individual corn kernels can be selected using a NIR detector. Selecting individual ears and/or kernels having an elevated oil content may not be cost effective. Preferably, corn seed producing corn plants that yield grain having elevated total oil concentrations can be planted and harvested using known farming methods. Methods for developing corn inbreds, hybrids, and populations that generate corn plants producing grain having elevated oil concentrations are known.

The moisture content of the corn grain can affect the flaking process. It may be necessary to adjust the moisture content of the corn grain to about 10% before flaking the seed. Optimizing the grain moisture content to facilitate efficient processing is within the knowledge of those of ordinary skill in the art.

The oil content of grain, including the fat content of a meal extracted from the grain, can be determined using American Oil and Chemical Society Official Method, 5th edition, March 1998, ("AOCS method") Ba 3-38. AOCS method Ba 3-38 quantitates substances that are extracted by petroleum ether under conditions of the test. The oil content or concentration is the weight percentage of the oil with respect to the total weight of the seed sample. Oil content may be normalized and reported at any desired moisture basis.

Unlike conventional oilseed flaking processing in which the hull component of the seed is removed before flaking, pericarp components of corn grain need not be removed before flaking, i.e., whole corn or cracked corn can be flaked. Corn grain is flaked to any useful size. For example, corn grain is flaked in one or more passes through flaking rollers to produce flakes having a final thickness of about 0.01 inches (0.25 mm), although other thicknesses may also be used. Useful flake thicknesses may depend on external limiting parameters such as the oil content of the corn, the moisture content, the corn type, e.g., dent or flint, and the oil extractor type.

Commercial-scale oilseed flaking and oil extraction methods as well as commercial-scale processing plants are known. In particular, suitable flaking and oil extraction methods include the methods and plants used for processing soybeans and similar oilseed types. Useful commercial-scale oilseed flakers can be obtained from French Oil Mill

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Machinery Company, Piqua, Ohio USA 45456-0920, ph. (937)-773-3420; Roskamp Champion, Waterloo, Iowa; Buhler, based in Switzerland and having offices in Plymouth, Minn. USA; Bauermeister, Inc., Germany; and Consolidated Process Machinery Roskamp Company, on the world wide web at <http://www.cpmroskamp.com>.

Corn oil is extracted from flaked grain in one or more extraction steps using any extraction method. Preferably, substantially all the oil is extracted in a single extraction step. Useful extraction methods include solvent extraction, hydraulic pressing, and expeller pressing. Useful solvents for solvent extraction can include hexane, n-hexane, isopropyl alcohol, supercritical carbon dioxide, and other similar solvents. For example, corn oil can be extracted from flaked grain using an n-hexane solvent extractor. Solvent extractors can include both percolation and immersion type extractors.

Substances exiting solvent-based extractors are referred to as wet flakes and miscella. Miscella is a mixture of extracted oil and solvent. The wet flakes are the material that remains after some or all of the solvent-soluble material has been extracted. Wet flakes also contain a quantity of solvent. Solvent is reclaimed from both miscella and wet flakes using known methods. For example, heat is applied to the wet flakes or miscella under a vacuum. Desolventized miscella is referred to as a crude oil that may be stored and/or undergo further processing. Crude oil obtained according to the invention may be refined to produce a final oil product. Methods for refining crude oil to obtain a final oil product are known to those of ordinary skill in the art. Crude oil isolated using the flaking methods described herein is of a high quality and requires fewer processing steps than is typically used in wet milling methods for processing corn grain to obtain corn oil.

Wet flakes are desolventized, dried and sized for storage and/or sale as a corn meal using methods known to those of ordinary skill in the art. The corn meal may also be mixed with other meal types or feedstuffs to create a complete feed or other meal or feed types.

~~Corn oil or meal quality is determined by evaluating one or more quality parameters such as the oil yield, phosphorus content, free fatty acid percentage, the neutral oil loss percentage, color, meal fat, fiber percentage, starch percentage, protein content, and moisture content. Any method can be used to calculate one or more of the quality parameters for evaluating the oil or meal quality.~~

The phosphorous concentration of crude oil can be determined using AOCS method Ca 12-55. AOCS method Ca 12-55 identifies the phosphorous or the equivalent phosphate content of an oil by ashing an oil sample in the presence of zinc oxide, followed by the spectrophotometric measurement of phosphorous as a blue phosphomolybdic acid complex. AOCS method Ca 12-55 is applicable to crude, degummed and refined vegetable oils. The phosphorous concentration is converted to phospholipid concentration, i.e., gum concentration, by multiplying the phosphorous concentration by 30.

The free fatty acid percentage of an oil can be determined using AOCS method Ca 5a-40. AOCS method Ca 5a-40 identifies the free fatty acids existing in the oil sample. AOCS method Ca 5a-40 is applicable to all crude and refined vegetable oils, marine oils and animal fats. The neutral oil loss during processing is determined by adding the gum percentage and the free fatty acid percentage together.

Oil color can be determined using AOCS method Cc 13b-45. AOCS method Cc 13b-45 identifies the color of an

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oil sample by comparing the oil sample with known color characteristics. AOCS method Cc 13b-45 is applicable to fats and oils provided no turbidity is present in the sample. Color values are quantitated by determining a red color value and a yellow color value using the AOCS method Cc 13b-45. Typically, crude corn oil isolated using wet milling methods has a red color value ranging from about 15 to about 20 and a yellow color value ranging from about 70 to about 80. Typically, crude corn oil isolated using dry milling methods has a red color value ranging from about 7 to about 10 and a yellow color value ranging from about 60 to about 70.

Color values are evaluated qualitatively by visual inspection of an oil. Typically, visual inspection results in an oil being classified as a light oil or a dark oil compared to a known oil color. For example, it is typical for crude oils isolated using wet milling techniques to be considered dark brown by visual inspection whereas oils isolated using dry milling techniques are considered lighter yellow. Corn oils isolated using flaking methods described herein have oil colors that are qualitatively considered light and quantitatively similar to crude corn oil color values for corn oils isolated using dry milling techniques.

~~Corn meal isolated using flaking methods as described herein can be a low fat corn meal. Several important quality parameters for oilseed meals include the fat, starch, protein, and moisture content of the resulting meal. Methods for evaluating quality parameters of oilseed meals including corn meals are known.~~

Corn meals derived using different methods or isolated at different times are compared by normalizing the meals to a common moisture content. The moisture content of an oilseed protein concentrate, such as a corn meal or whole corn, is determined using AOCS method Ba 2b-82. The crude fiber content of corn meal is determined using AOCS method Ba 6-84. AOCS method Ba 6-84 is useful for grains, meals, flours, feeds and all fiber bearing material from which the fat can be extracted leaving a workable residue. Crude protein content of corn meal is determined using AOCS method Ba 4c-93. The starch content of corn meal is determined using the Standard Analytical Methods of the Member Companies of the Corn Refiners Association Incorporated, 2d Edition, Apr. 15, 1986, method A-20 ("Corn Refiner's method A-20").

It is to be understood that the analytical methods provided herein are illustrative examples of useful methods for computing various quality parameters for the oils and meals described herein. Other suitable methods are known and may be used to compute the quality parameters disclosed and claimed herein.

Novel methods for processing corn described herein facilitate a novel method for doing business, which can include the following steps. Corn seed that is effective for developing into a corn plant that produces corn grain having a total oil content of at least about 8% is made, used, sold or offered for sale. Advertisements, marketing strategies, or other suitable promotions concerning the corn seed are disseminated to the relevant audience. The advertisements indicate that corn grain harvested after planting the corn seed can be processed using flaking techniques or methods. ~~The advertisements can further indicate that the flaking methods facilitate extracting a corn oil or can indicate that suitable flaking methods include methods that are used for processing oilseeds such as soybeans.~~ Such a method is useful for marketing or selling corn seed to consumers in regions where oilseed processing plants that utilize flaking

methods are physically located. The relevant audience includes farmers, seed corn dealers, oilseed processors, and other persons involved in the oilseed industry. Suitable advertisements include radio and television advertisements, labels or other indicia present on packages of corn seed, promotional meetings, random or directed mailings, hand bills, and any other form of communication directed to the relevant audience.

In another aspect, a novel method of doing business comprises the steps of buying, purchasing, or offering to buy corn grain having a high oil content for the purpose of processing the purchased grain by flaking the grain and extracting an oil therefrom. In so doing, a business may advertise that it is a facility that flakes high oil corn grain. In particular, the facility may flake corn for extracting corn oil and/or producing corn meal.

An article of manufacture can include packaging material and seed corn contained within the packaging material. Such seed corn produces a corn plant that yields corn grain having an oil content greater than about 8% which may be processed by flaking the corn grain and extracting an oil. Also included with the packaging material is a label or package insert that indicates that an oil can be extracted from the resulting corn grain by flaking the corn grain and extracting an oil or described herein. Any known packaging and printing method may be used to prepare the packaging material of the article of manufacture.

EXAMPLE 1

Processing High Oil Corn Using A Flaking Method

Shelled kernels of individual ears of yellow dent corn were screened for a total oil content greater than about 7% oil using a Perten bulk near infrared (NIR) seed tester™ (model 9100-H.F) Perten Instruments, P.O. Box 7398, Reno, Nev. 89510. Kernels from the ears having at least a 7% oil content were screened further for individual kernels having an oil content of at least 13% oil in a Brimrose seedmeister™ single kernel NIR tester (Brimrose Corp., Baltimore, Md.). The kernels were stored at a moisture content of about 13.5%. At the time of processing, the moisture content of the seed was about 10%.

A bench scale flaking apparatus containing a two inch stainless steel rod and plate was used to flake the whole corn grain. The whole corn grain sample was passed through the rollers four times to obtain a final flake thickness of about 0.01 inches. A miscella was extracted from the flaked corn grain using hot (60–65° C.) n-hexane and a Kimble™ model 585050 Soxhlet extractor. The resulting miscella and corn meal were desolventized. The miscella was desolventized by heating the miscella to 70° C. under a vacuum of 25 inches mercury. The corn meal was desolventized according to AOCS method Ba 2a-38.

The total recovered oil was determined to be 14.74% of the whole corn grain sample. The phosphorus content of the desolventized crude oil was determined to be 365 parts per million (ppm) using AOCS method Ca 12-55. The phospholipid concentration was determined to be 1.095% (0.0365%*30). The free fatty acid content was determined to be 0.2% using AOCS method Ca 5a-40. The neutral oil loss during processing was determined to be 1.3% (1.095%+0.2%). Using the same methods, crude oil extracted from normal, i.e., 3–4% total oil content, corn grain using conventional wet milling methods can be expected to have a phosphorus content from about 600 ppm to about 800 ppm, a free fatty acid concentration from about 0.5% to about 1.0

percent, and a neutral oil loss during processing ranging from about 3% to about 4%.

The color of the crude oil was visually evaluated and determined to be a light yellow color compared to a crude oil isolated using conventional wet milling methods, which was a dark brown color.

The desolventized corn meal was characterized using AOCS methods Ba 3-38, Ba 2b-82, Ba 6-84, and Ba 4e-93, and Corn Refiner's Method A-20. When normalized to a 10% moisture content, the corn meal had a 3.2% fiber content, a 65% starch content, and a 14% protein content. Meal fat was determined to be 1.07% using AOCS method 3-38. For comparison, corn gluten feed created using conventional wet milling methods and normalized to a 10% moisture content can be expected to contain an oil content of about 4%, a protein content of about 20%, and a fiber and other carbohydrate content of about 60%. Also for comparison, corn gluten meal created using conventional wet milling methods and normalized to a 10% moisture content can be expected to contain an oil content of about 3%, a protein content of about 60%, and a fiber and other carbohydrate content of about 22%.

To the extent not already indicated, it also will be understood by those of ordinary skill in the art that any one of the various specific embodiments herein described and illustrated may be further modified to incorporate features shown in other of the specific embodiments.

The foregoing detailed description has been provided for a better understanding of the invention only and no unnecessary limitation should be understood therefrom as some modification will be apparent to those skilled in the art without deviating from the spirit and scope of the appended claims. As such, other aspects, advantages, and modifications are within the scope of the following claims.

What is claimed is:

1. A method for processing corn grain comprising the steps of:
 - a) flaking corn grain; and
 - b) extracting an oil from said flaked corn grain, said corn grain having a total oil content of at least about 8%.
2. The method of claim 1 wherein said corn grain is whole corn grain.
3. The method of claim 2 wherein said corn grain is a cracked corn grain.
4. The method of claim 1 wherein said corn grain has a total oil content of at least about 14%.
5. The method of claim 1 wherein said corn grain has a total oil content of at least about 12%.
6. The method of claim 1 wherein said corn grain has a total oil content of at least about 10%.
7. The method of claim 1 wherein said corn grain has a total oil content from about 12% to about 30%.
8. The method of claim 1 wherein said extracting step comprises pressing said flaked corn grain.
9. The method of claim 1 wherein said extracting step comprises solvent-based oil extraction of said flaked corn grain.
10. The method of claim 9 wherein said solvent is selected from the group consisting of hexane, n-hexane, isopropyl alcohol, and supercritical carbon dioxide.
11. The method of claim 9 wherein said solvent comprises n-hexane.
12. The method of claim 9 wherein said extracting step produces a miscella and a corn meal.
13. The method of claim 12 wherein said corn meal comprises a fiber content of about 3%, a starch content of

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about 65%, and a protein content of about 14%, at a moisture content of about 10%.

14. The method of claim 12 wherein said corn meal comprises a fiber content of about 3%, and a protein content of about 14%, at a moisture content of about 10%.

15. The method of claim 12 wherein said corn meal comprises a fiber content of at least about 3%, at a moisture content of about 10%.

16. The method of claim 12 further comprising the step of desolventizing said miscella to produce a corn oil.

17. The method of claim 16 wherein said corn oil has a phosphorous content of less than about 500 parts per million.

18. The method of claim 16 wherein said corn oil has a free fatty acid content of less than about 0.3%.

19. The method of claim 1 wherein said corn oil has a neutral oil loss of less than about 2%.

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20. The method of claim 1 wherein said corn oil has a light yellow color.

21. The method of claim 16 wherein said corn oil has a yellow color value ranging from about 60 to about 70 and a red color value ranging from about 7 to about 10, as determined by American Oil and Chemical Society method Cc 13b-93.

22. The method of claim 1 wherein said method is effective for processing at least about 100 tons of corn per day.

23. The method of claim 1 wherein said method is effective for processing from about 100 tons of corn per day to about 3,000 tons of corn per day.

* * * * *

APPENDIX G



US006313273B1

(12) **United States Patent**
Thomas et al.

(10) Patent No.: **US 6,313,273 B1**
(45) Date of Patent: **Nov. 6, 2001**

(54) **SOY PROTEINS AND METHODS FOR THEIR PRODUCTION**

(75) Inventors: Ronald L. Thomas, Clemson, SC (US);
Louis I. Ndiffe, Columbus, OH (US);
Hilary Shallo, Naperville, IL (US);
Lynn P. Nelles, St. Charles, MO (US)

(73) Assignee: Abbott Laboratories, Abbott Park, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/382,966

(22) Filed: Aug. 25, 1999

(51) Int. Cl.⁷ A23J 1/14; A61K 35/78;
A61K 35/80; C07K 14/00

(52) U.S. Cl. 530/378; 530/370; 530/372;
530/376; 530/377; 530/378; 530/414; 530/418

(58) Field of Search 530/370, 372,
530/376, 377, 378, 414, 418; 514/2

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Primary Examiner—Karen Cochrane Carlson

Assistant Examiner—Stephen Tu

(74) Attorney, Agent, or Firm—J. Michael Dixon

(57)

ABSTRACT

A high quality soy protein concentrate (SPC) was produced by a process of enzyme treatment combined with ultrafiltration. Soy flour, the starting material, was enzymatically treated with commercial pectinases and diafiltered with a porous stainless steel ultrafiltration system. The resulting product had reduced levels of phytic acid and nucleic acids due to contaminant phytase and nuclease activity in the pectinase enzymes. The functionality of the SPC was improved due to increased solubility compared to conventional soy isolates produced by acid precipitation. High performance liquid chromatography gel filtration profiles indicated that the proteins in the SPC remained intact. The SPC also had reduced flavor when compared to the original soy flour according to gas chromatography flavor profiles and sensory evaluation.

17 Claims, 12 Drawing Sheets

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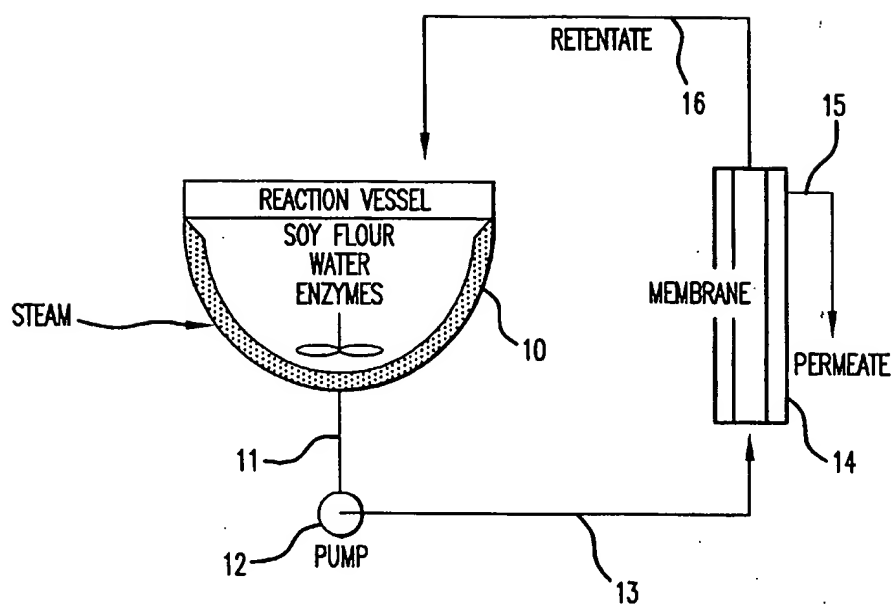


FIG.1

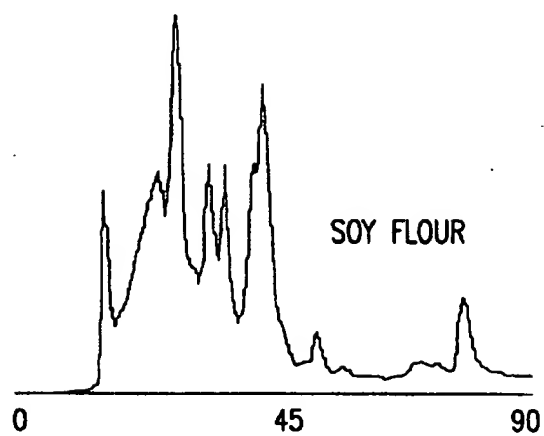


FIG. 2A

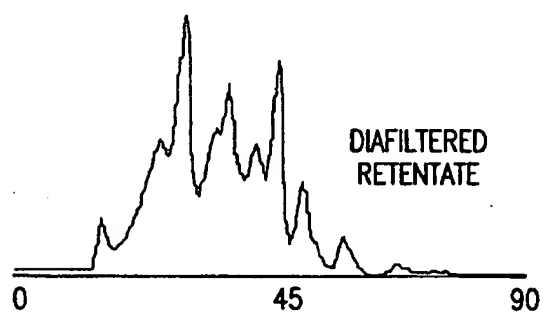


FIG. 2B

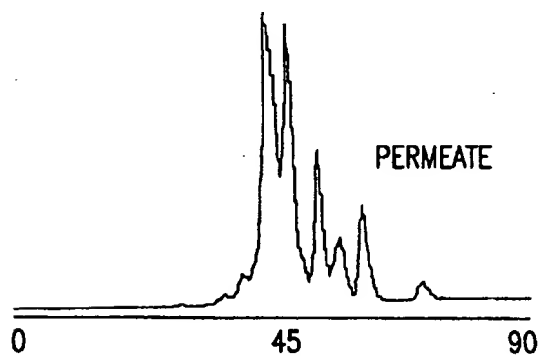


FIG. 2C

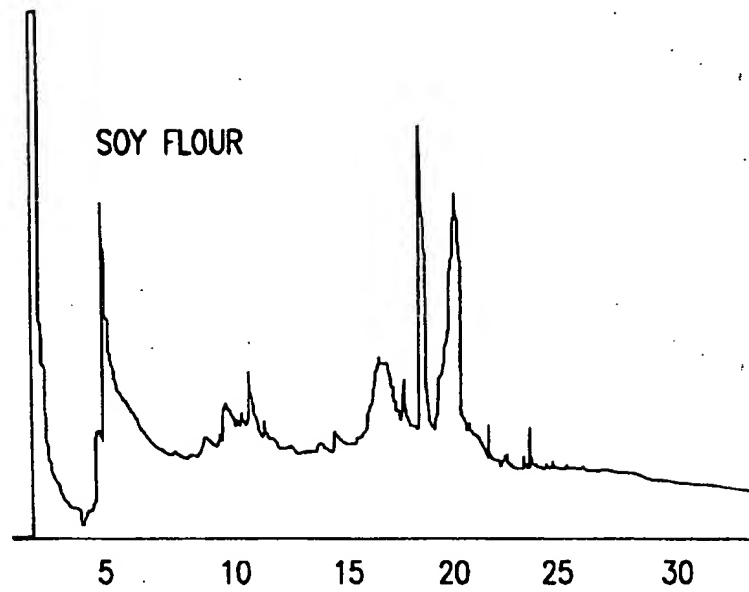


FIG. 3A

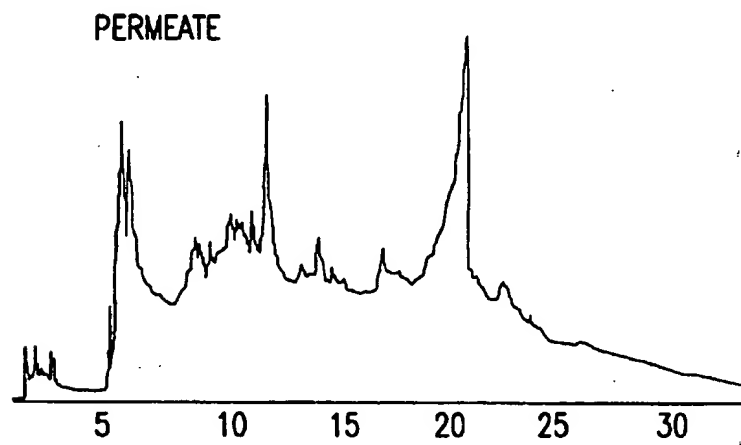


FIG. 3B

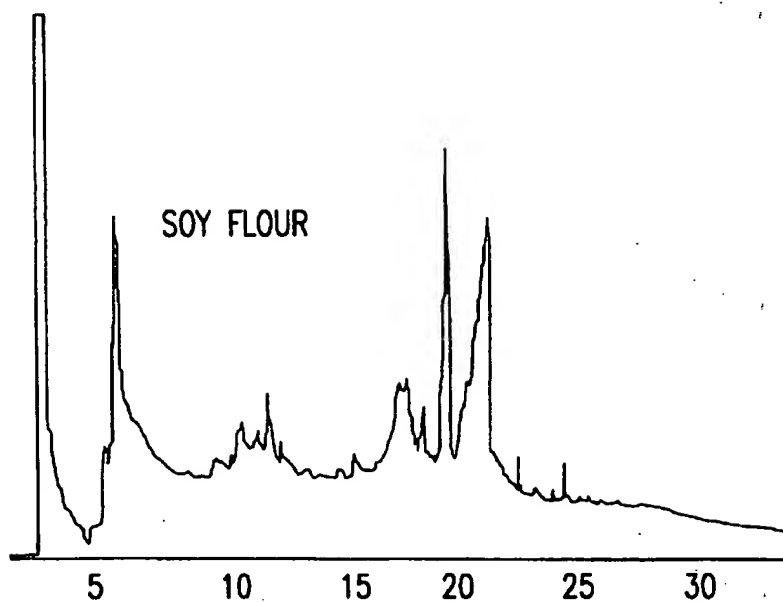


FIG. 4A

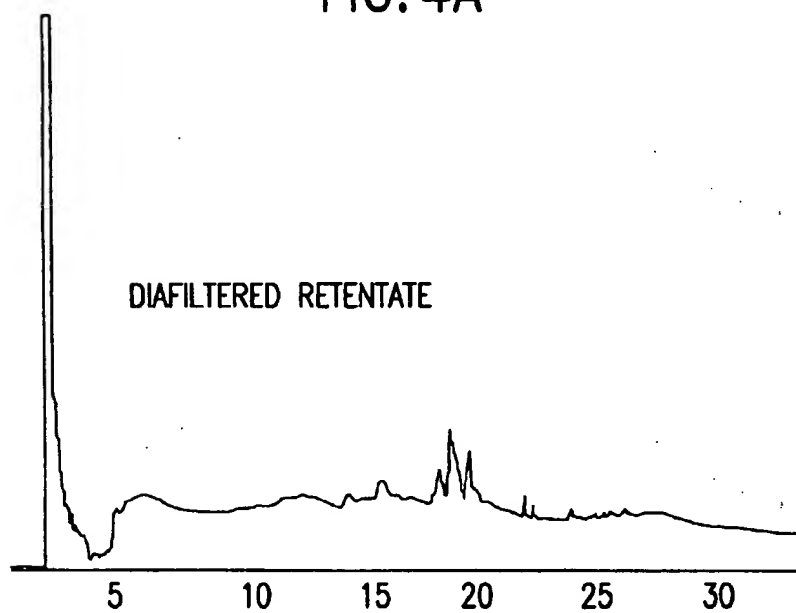


FIG. 4B

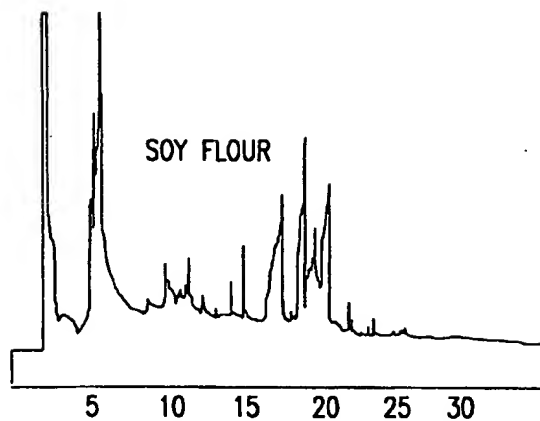


FIG. 5A

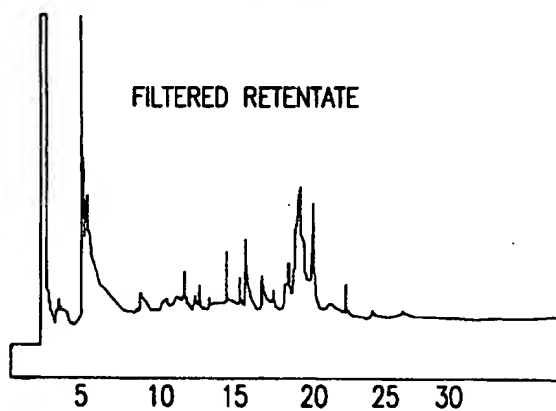


FIG. 5B

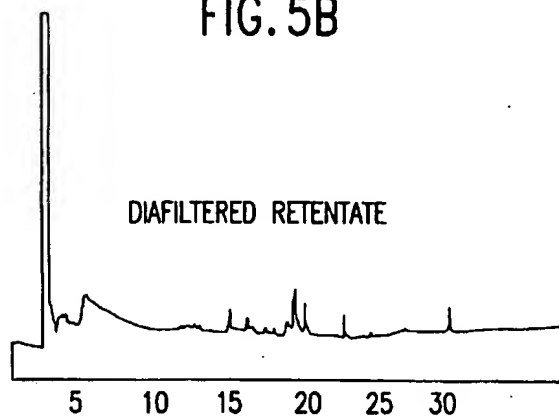


FIG. 5C

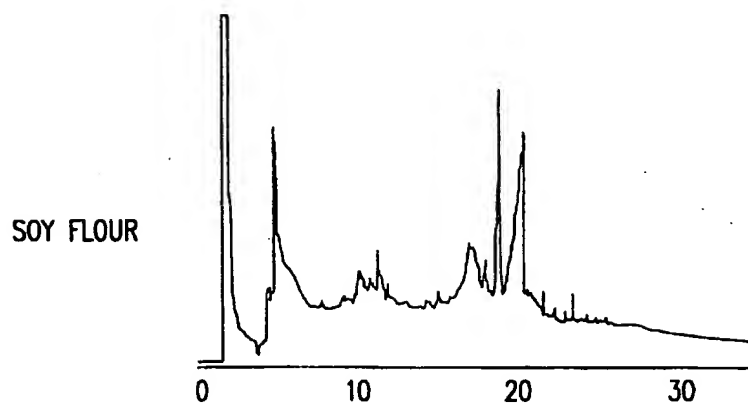


FIG. 6A

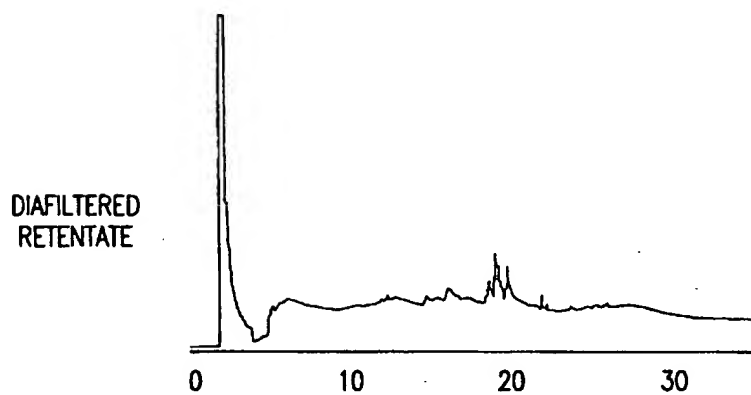


FIG. 6B

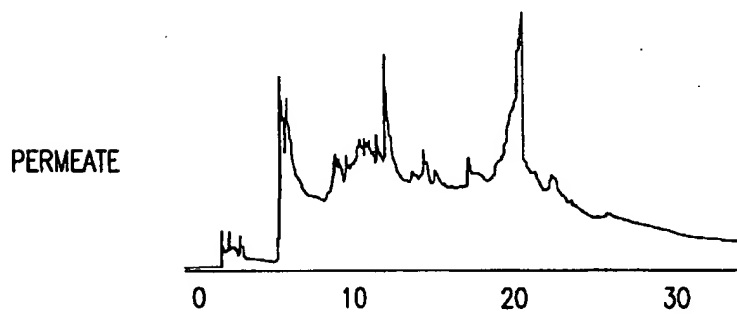


FIG. 6C

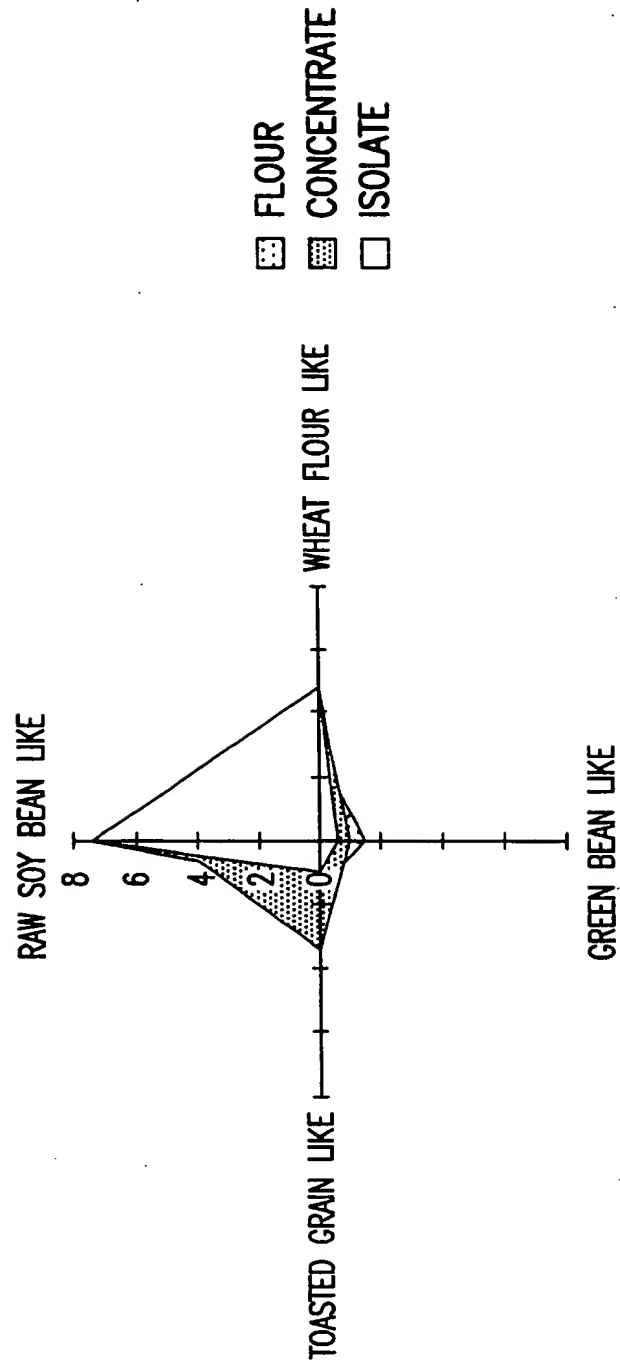


FIG. 7

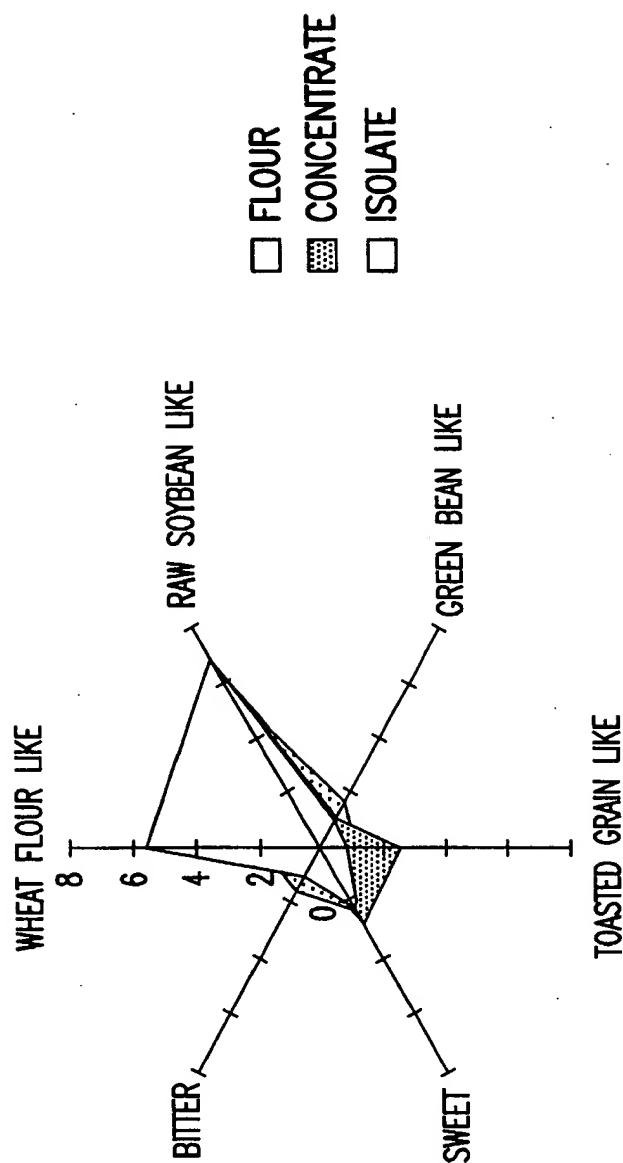


FIG. 8

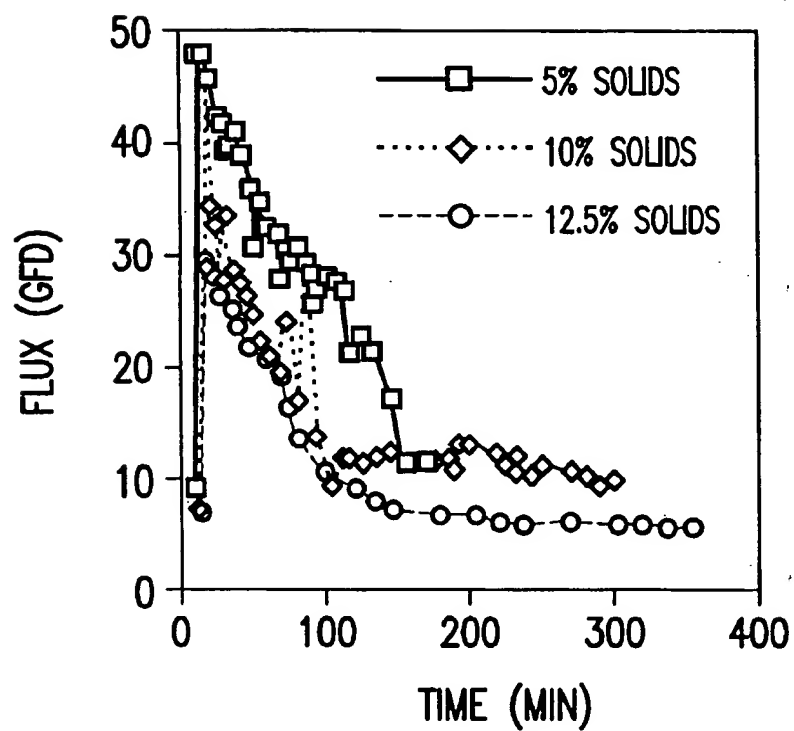


FIG.9

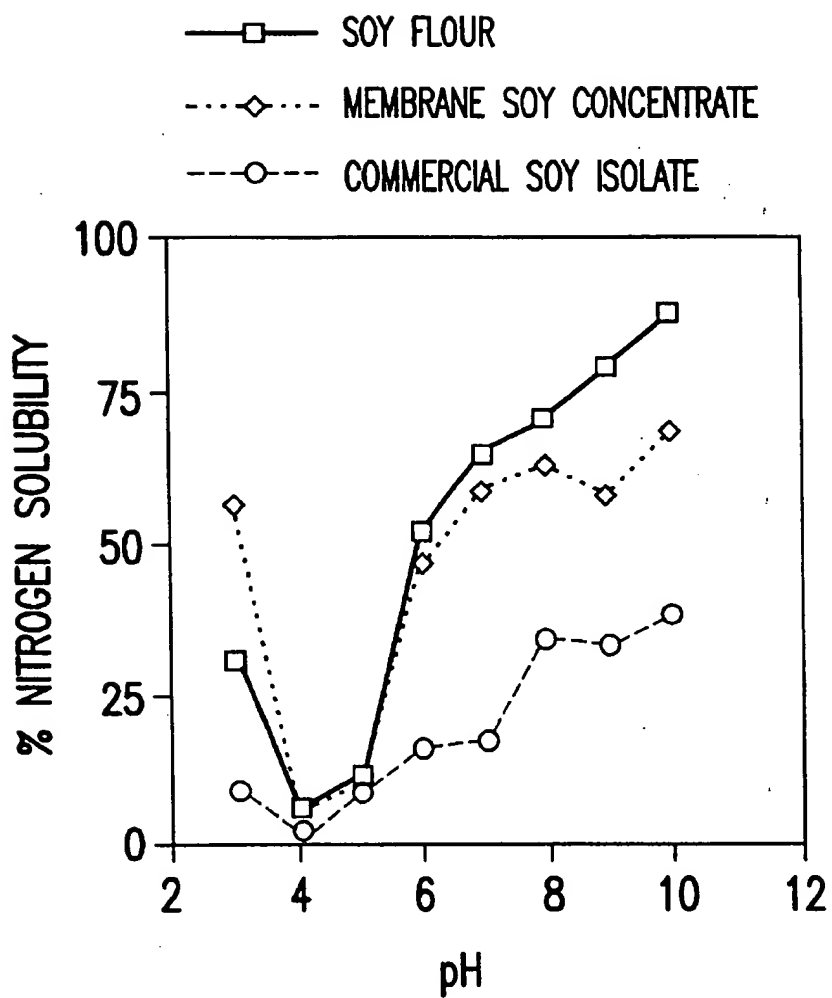


FIG.10

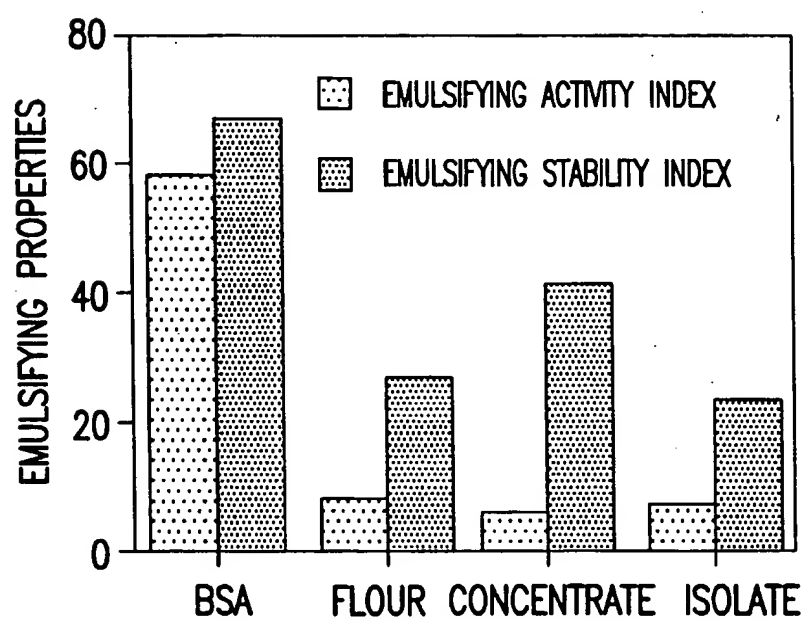


FIG. 11

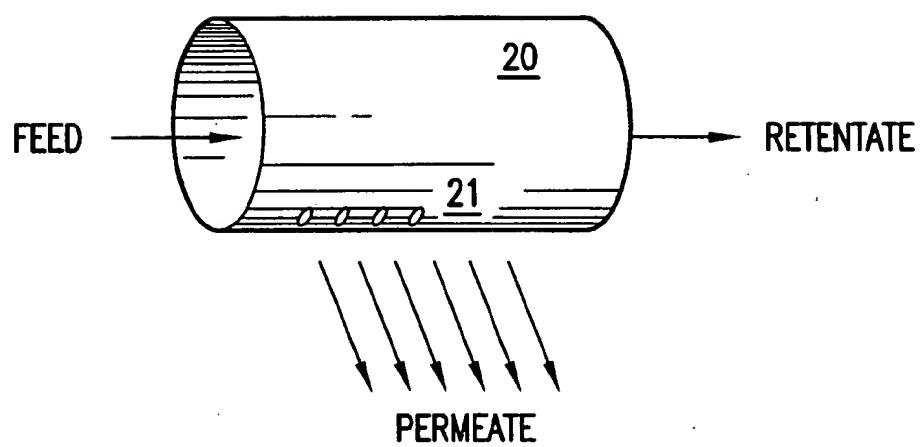


FIG. 12

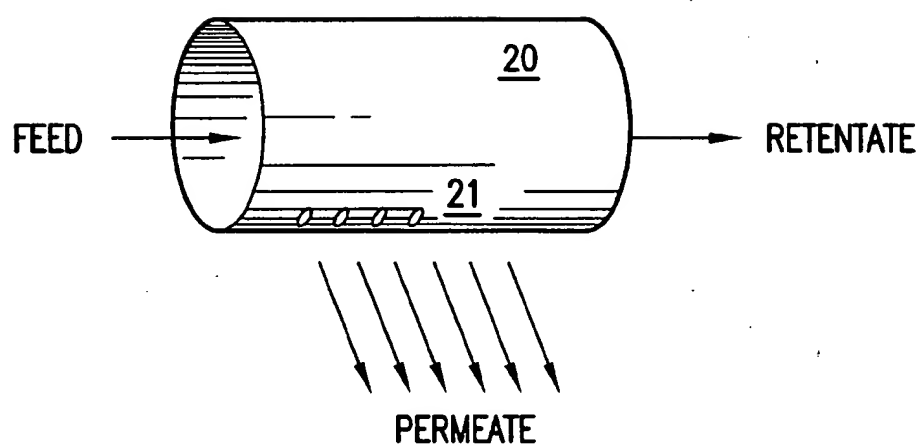


FIG. 12

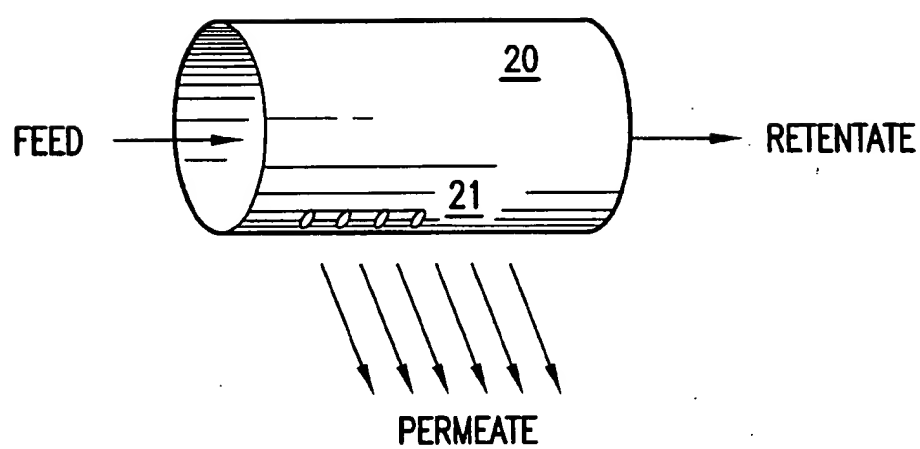


FIG. 12

cating some mineral binding to proteins since minerals should have been freely permeable to the membrane. The final product in this study contained 59.7% protein, 34.2% fat, 2.85% ash, 0.64% oligosaccharides and 0.065% phytic acid.

In an additional study, Omosaiye, O., Cheryan, M., (1979a) Low-phytate, full-fat soy protein product by ultrafiltration of aqueous extracts of whole soybeans, *Cereal Chemistry*, 56(2): 58-62, used a two step process which included ultrafiltration to produce a soy protein isolate low in phytic acid. The first step consisted of extracting the beans. This extract was subjected to ultrafiltration. The phytate removal depended on the pH of the ultrafiltration solution. The greatest phytate removal occurred at pH 6.7. Less phytate was removed at pH 2.0, pH 8.0 and pH 10.0. These results may in part be explained by phytate-protein interactions. At pH 6.7, the phytate appeared to be water soluble, did not have a strong electrostatic attraction and the salt linkages were weak. The optimum pH for phytate removal was found to be the same as the pH for protein water extracts.

Nicholas, D. J., Cheryan, M. (1981) Production of soy isolates by ultrafiltration: Factors affecting yield and composition, *Journal of Food Science*, 46: 367-372, studied the factors affecting the yield and composition of soy protein isolates during an ultrafiltration process. The starting material was an extract of defatted soy flour. The molecular weight cut-off of the membrane was 50,000. In order for the ultrafiltration step to produce a product with a protein content of 90%, over 80% of the non-protein solutes needed to be removed. The starting material had a protein content of 65%. The highest protein content obtained was 84% on a dry weight basis. Therefore, the ultrafiltration step did not fractionate the compounds to the degree necessary to produce a soy protein isolate. Pumping problems and severe membrane fouling were cited as problems. As observed in other studies (Omosaiye and Cheryan, (1979b), supra) the mineral content did not decrease according to predicted permeability of the membrane, perhaps due to mineral-protein binding. The highest protein yield obtained was 86%.

In summary, the prior art shows that attempts have been made to: 1) produce soy protein isolates and concentrates utilizing ultrafiltration, and; 2) to remove phytate and volatiles from soy proteins. Such attempts have met with limited success. Several authors report severe fouling of the filtration membranes. Fouling is the build up of substances on the surface of the membrane. This prevents the membrane from performing its function of separating molecules on the basis of size. The presence of complex polysaccharides of large molecular weight has often been cited as the source of the fouling. The complex interaction between phytate and protein has been a further source of difficulty. Authors have reported using acid treatments prior to ultrafiltration to disrupt this interaction. The acidification however leads to a partial denaturation of the protein with corresponding adverse effects on its performance.

Thus a need exists in the art for a ultrafiltration process that can be used to produce soy protein on a commercial scale. A further need exist in the art for soy protein having reduced levels of phytoestrogens, phytate, and nucleic acids. A further need exists for a process for producing soy proteins isolates and concentrates that does not subject to the soy proteins to acidic conditions, since such conditions produce a partial denaturation of the protein.

SUMMARY OF THE INVENTION

In accordance with the present invention, a new process for isolating soy proteins has been developed. The new

process comprises initially contacting the soy protein source with one or more enzymes containing nuclease and phytase activity for a sufficient period of time to allow the occurrence of an enzymatic treatment. After the enzymatic treatment, the soy protein source is subjected to an ultrafiltration. Following ultrafiltration, the partially isolated soy protein is diluted and subjected to a second ultrafiltration (diafiltration).

In its more preferred embodiments, the process is directed to the production of soy protein concentrates and isolates. Typically a soy flour will be contacted with commercial grade enzymes (pectinases) under conditions suitable for an enzymatic reaction. The product of the enzymatic reaction will be pumped directly under pressure into a tubular housing unit which contains one or more metallic oxide ultrafiltration membranes. Typically these ultrafiltration membranes are secured along the inside surfaces of the housing unit. After the ultrafiltration is completed, the resulting retentate is diluted with an aqueous solution and subjected to a diafiltration in the same ultrafiltration unit. The aqueous solution may be added continually or in a batchwise manner.

The process produces a soy protein having numerous advantages over the soy proteins of the prior art. The soy protein has reduced levels of phytate, isoflavone, and nucleic acids. Levels of phytate in the soy protein produced via the invention are typically reduced by a factor of at least 50%, and more preferably at least 70% and even up to 90-99% (on a weight/weight basis), when compared with soy proteins produced using standard techniques. Typically, the soy proteins will contain no more than about 5 mg of phytate per gram of protein and more preferably no more than about 2 mg of phytate per gram of protein.

Levels of isoflavone in the soy protein produced via the invention are also reduced when compared with currently available soy proteins. Isoflavone levels are typically reduced by a factor of at least 50% and more preferably about 70% (on a weight/weight basis). Absolute levels can vary depending upon the content of isoflavone in the soy beans which varies due to a number of factors such as seasonal variation, growing conditions, source of seed, etc.

Levels of nucleic acid in the soy protein are also reduced. This amount can vary, but typically nucleotide levels will be reduced by a factor of at least 30% (by weight) and more preferably about 50%. The absolute amount of nucleic acid can vary, but typically, the soy protein will contain no more than about 1 mg of ribonucleic acid per gram of protein and more preferably no more than about 0.4 mg of ribonucleic acid. Further the flavor of the soy protein is enhanced. This is due to the removal of the volatile components in soy associated with undesirable flavours.

In addition to having reduced levels of phytate, isoflavone, and nucleic acids; the soy protein has superior emulsifying capacities. Soy protein produced via prior art methods are exposed to acidic washes. The acidic treatment has a tendency to denature the protein and reduce its capability to serve as an emulsifier in infant formula. The soy protein of this invention has a water hydration capacity of about 2 to about 5 and more preferably about 2.6% which is not different from soy flour (see Quinn, J. R. and Paton, D. 1979, A practical measurement of water hydration capacity of protein materials. *Cereal Chem.* 56: 38-40 for methodology). Surface hydrophobicity of soy protein produced via the invention is typically no greater than about 30, is more typically in the range of about 15-25 and more preferably about 20 (see Hayakawa, S. and Nagai, S. 1985,

Relationships of hydrophobicity and net charge to the solubility of milk and soy proteins. *Journal of Food Science* 50: 486-491 for methodology). Nitrogen solubility of the soy protein produced via this invention, when measured at a pH of 7.0 is typically no less than about 40 w/w%, more typically ranges from about 50-70 w/w% and more preferably is no less than about 57 w/w% (see Bera, M. B. and Mukherjee, R. K. 1989, Solubility, emulsifying and foam properties for rice bran protein concentrates. *Journal of Food Science* 50: 142-145 for methodology). Soy protein produced via the methodology of this invention will have an emulsifying capacity of no greater than about 7 meters square per gram (m^2/g), more typically about 4-7 m^2/g and most preferably about 6.0 m^2/g (see Pearce, K. N. and Kinsella, J. E. 1978. Emulsifying properties of proteins; Evaluation of a turbidimetric technique *Journal of Agricultural Food Chem.* 26: 716-723 for a description of the methodology) which is not significantly different from that of soy flour and commercial isolate. The stability of the emulsion formed is also important in determining the emulsifying properties. Soy protein produced via this invention has an emulsion stability index of greater than 30 m^2/g , more typically from 30-50 m^2/g and more preferably about 40 m^2/g .

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a schematic diagram of the ultrafiltration membrane system showing the flow and separation of permeate and retentate streams.

FIG. 2 is a High Performance Liquid Chromatogram—Gel Filtration profile of Soy Flour, Diafiltered Retentate and Permeate.

FIG. 3 is a Gas Chromatogram (GC) of Soy Flour and Permeate.

FIG. 4 is a GC of Soy Flour and Diafiltered Retentate.

FIG. 5 is a GC of Soy Flour, Filtered Retentate and Diafiltered Retentate.

FIG. 6 is a GC of Soy Flour, Diafiltered Retentate and Permeate.

FIG. 7 is a spider plot describing the aroma of Soy Flour, Membrane Soy Concentrate and Commercial Soy Isolate.

FIG. 8 is a spider plot describing the flavor of Soy Flour, Membrane Soy Concentrate (produced via the invention) and Commercial Soy Isolate.

FIG. 9 is a graph which shows the effect of solids concentration on flux.

FIG. 10 is a graph showing the comparison of nitrogen solubility among Soy Flour, Membrane Soy Concentrate and Commercial Soy Isolate in the pH range of 3 to 10.

FIG. 11 is a bar graph comparing the emulsifying properties of Bovine Serum Albumin, Soy Flour, Membrane Soy Concentrate and Commercial Soy Isolate.

FIG. 12 is a schematic diagram of the metallic oxide ultrafiltration membrane.

DETAILED DESCRIPTION

As used in this application;

- a) "soy protein concentrate" refers to a composition which contains at least 70% soy protein as measured on a dry weight basis using the Microkjeldahl method for determining nitrogen (AOAC. 1975. *Official Methods of Analysis*, Section 47.021 Association of Official Analytical Chemists, Washington DC). The protein content was calculated using the conversion factor of 6.25.

- b) "soy protein isolate" refers to a composition which contains at least 90% soy protein as measured on a dry weight basis using the Microkjeldahl method for determining nitrogen (AOAC. 1975. *Official Methods of Analysis*, Section 47.021 Association of Official Analytical Chemists, Washington DC). The protein content was calculated using the conversion factor of 6.25.

- c) "ultrafiltration" refers to a process in which the source of soy material is pumped under pressure against a metallic oxide membrane and in which molecules having a molecular weight of less than 6500 daltons will pass thru the membrane into the filtrate and molecules having a molecular weight of 6500 daltons or greater will be retained by the membrane in the retentate.

- d) "diafiltration" refers to a process in which the retentate from the ultrafiltration is rediluted with an aqueous solution and the admixture is brought into contact with the ultrafiltration membrane and subjected to a second ultrafiltration.

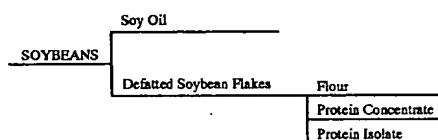
- e) "nucleic acids" refers to total phosphorus nucleotides (TPANT), total free nucleic acids and ribonucleic acids. "Levels of nucleic acids" refers to a determination carried out as described in *American Journal of Clinical Nutrition*; 61(6): 1224-1230, 1995.

- f) "isoflavones" refers to daidzein, genistein and glycitein. "Levels of isoflavones" refers to a determination by the method of Wang and Murphy, *Journal of Agricultural Food Chem.* 42: 1666-1673 (1994).

- g) "phytate" refers to phytic acid. "Phytate levels" refers to a determination by the method of McChance and Widdelwson, *The Biochemical Journal*, 29:2694 (1935) and Fiske, and Subbarrow, *Journal of Biochemistry*, 66:375 (1925).

As noted above, the present invention is directed to a multistep process for isolating and purifying soy proteins. The soy protein is isolated from the soybean. The soybean is an excellent source of high quality protein, where about 38% to 40% of the soybean is protein. Briefly (as shown in Scheme I), the processing of soybeans involves the extraction of the oil from the dehulled, and cracked soybeans leaving the defatted soybean flakes.

Scheme I
Soybean Processing



The defatted soybean flakes are typically milled into flours. As described above, they may be further processed into protein concentrates or isolates. One aspect of this invention is directed to methods for the production of these concentrates and isolates.

Typically defatted soy bean flakes or soy flours will be the source of soy protein in the inventive process. However soy concentrate may be utilized as well.

The initial step of the process is an enzymatic treatment in which the soy protein source is contacted with an appropriate enzyme preparation containing both phytase and nuclease activity. The enzyme, or enzymes, used in the process must provide both nuclease activity and phytase activity. It is preferable to use a single enzyme possessing

both activities. A process using a single enzyme possess the advantages of saving on processing time and reducing two constituents like phytate and nucleic acids in the same enzymatic treatment. A single enzyme also reduces the potential of introducing allergens into the product.

The level of phytase activity contained within the enzyme can vary widely. Typically the enzyme will contain at least 56 units phytase activity per milliliter of enzyme and more preferably from about 220 phytase activity units per milliliter of enzyme to about 730 phytase activity units per milliliter. The level of nuclease activity may vary because nuclease are ubiquitous. The commercial enzymes, crystalzyme and pectinase used in this invention possess nuclease activity.

One example of an enzyme possessing such dual activities includes commercial grade pectinases. Examples include pectinase from Sigma, Crystalzyme from Valley Research, Enzeco Pectinase CO or PL from Enzyme Dev. Co., Clarex L or ML from Genecor or Peelzyme from Novo Nordisk.

Alternatively, single enzymes possessing nuclease or phytase activity can be used. Sources of phytase activity include microorganisms like bacteria and fungi. Sources of nuclease activity also include bacteria and fungi.

The enzymatic treatment is carried out using techniques well known to those skilled in the art. The reactants are assembled together in an appropriate mixing vessel. Any vessel suitable for enzymatic reactions may be utilized. In the inventions most preferred embodiment, the reactants are admixed together in a vessel connected directly to the ultrafiltration apparatus so it may be pumped directly into the filtration membranes at the conclusion of the enzymatic reaction.

The soy flour (or other source of soy protein) will be diluted with an aqueous solution in the reaction vessel. Typically only water will be used, but dilute alcohol may also be used. The quantity of soy flour can vary widely. Typically the soy source will be present in the reaction vessel in an amount ranging from about 5% to about 12.5% and more preferably about 10%, based upon weight. The quantity of enzyme can vary, but will typically be present in an amount of at least 0.3% v/v and more preferably about 0.3% to about 0.9% v/v based upon the phytase activity of the enzyme and the quantity of the soy material. The enzyme reaction will be carried out at a temperature of about 84.50° F. to about 1220° F. and more preferably about 98.60° F. to about 107.60° F. The enzymatic reaction will be allowed to continue for a period of time of at least about three hours and optionally longer. At the conclusion of the enzymatic reaction, the solution is pumped directly into the ultrafiltration apparatus.

The next step in the process is the ultrafiltration of the enzyme treated soy flour solution. The ultrafiltration will be carried out using techniques generally known in the art. A detailed discussion of ultrafiltration techniques and apparatuses can be found in the "Ultrafiltration Handbook" by Munir Cheryan, Technomic Publishing Co. Lancaster, Pa. (which is hereby incorporated by reference).

Any of the various ultrafiltration devices that are commercially available may be utilized in the practice of this invention. Examples of suitable ultrafiltration devices include those described in U.S. Pat. No's. 4,716,044; 4,200,533; 5,1130,237; and 4,897,465, the contents of which are hereby incorporated by reference.

Ultrafiltration is typically carried out with modular units. A module will contain numerous tubes through which the relevant fluid will be pumped. The tubes will be impregnated with the ultrafiltration membranes. Molecules having a size (molecular weight) of less than about 6500 daltons will pass

thru the membranes as the permeate and will be channeled away. Molecules having a size greater than 6500 daltons will not pass thru the membrane but will be retained by the module as the retentate.

The ultrafiltration membranes impregnating the tubes should be manufactured from metallic oxides. Examples of suitable metallic oxides include titanium dioxide, but the invention is not limited to such materials. In the invention's most preferred embodiment, the membranes will be manufactured from sintered titanium dioxide. One example of a suitable ultrafiltration device is the Scepter 316L which is manufactured by Graver Technologies of Seneca, S.C.

FIG. 1 provides an illustration of an exemplary ultrafiltration device according to the present invention. Reaction Vessel 10 is connected to an outflow tube 11 which is connected to a pump 12. Pump 12 is connected to an outflow tube 13 which is connected to ultrafiltration system 14 in which are multiple ultrafiltration membranes as depicted in FIG. 12. Ultrafiltration system 14 is connected to outflow tube 15 from which the permeate from the ultrafiltration system is directed. Ultrafiltration system 14 is also connected to outflow tube 16 by which the retentate is pumped from the ultrafiltration system and returned to reaction vessel 10 for dilution prior to diafiltration. FIG. 12 provides an illustration of ultrafiltration membrane according to the invention. Tube 20 is impregnated with multiple membranes 21.

The process of the invention generally works in the following manner. The enzyme treated soy protein is placed in reaction vessel 10 and is pumped under pressure through output tubes 11 and 13 into ultrafiltration system 14. The enzyme treated soy is isolated and purified inside ultrafiltration system 14. As is depicted in FIG. 12, the undesired constituents such as isoflavones, phytate, volatiles, and nucleic acids flow through membranes 21 as the permeate and are directed away from tube 20. The desired soy proteins are retained in tube 20 as the retentate. The undesired permeate leaves the ultrafiltration device through tube 15. This permeate may be discarded or retained for further processing, such as isolating the isoflavones. The desired retentate will leave the ultrafiltration device through tube 16.

The actual ultrafiltration process is carried out using techniques known to those familiar with ultrafiltration. The permeability of membranes to water is one important variable in how the ultrafiltration is carried out. Permeability serves as an indicator of relative pore size, and thus represents rejection characteristics and rate of permeate flow. A change in water permeability also serves as a reference to indicate when it is time to clean the membranes to return them to their original state.

The process should be carried out so that the ultrafiltration membrane has an initial permeability to water of about 0.55 to about 0.58 gallons/sq. ft./day (gfd). This may be determined by the following formula:

$$P = \frac{\text{Permeate flux}}{\text{Inlet Pressure}}$$

in which permeate flux is the number of gallons of water passing through a square foot of membrane area per day and inlet pressure is maintained at a given constant and is measured in pounds/square inch (psi). Throughout the ultrafiltration, the permeability should be maintained within a range of about 0.04 to about 0.3 and more preferably about 0.10 gfd.

The concentration of the soy protein will be adjusted to optimize the ultrafiltration. The soy protein source will be present in the ultrafiltration solution at a concentration of about 5 w/w % to about 20 w/w % and more preferably at

a concentration of about 5 w/w % to about 10 w/w % during the ultrafiltration. Typically the ultrafiltration solution will be water, but buffered solutions in the pH range of 6.0 to 7.0 may also be used.

It is important to point out that one of the advantages of the invention is the elevated concentrations at which the ultrafiltration may be carried out. In the prior art processes involving soy protein, it was not possible to exceed a concentration of 6.9 w/w % in the solution being ultrafiltered. However, the enzymatic pretreatment allows the ultrafiltration to be run at concentrations of up to about 20 w/w %. Such a result was entirely unexpected. Such a result also allows the ultrafiltration device to process a greater amount of soy protein in a given period of time.

The pH of the ultrafiltration solution should be maintained in a range of from about 7.0 to about 10.0, more preferably about 8.0 to about 9.0, and most preferably about 8.8 to 9.0. As noted above, an advantage of the invention is that soy protein isolates and concentrates are not subjected to an acidic precipitation step. Thus it is important that the pH of the soy filtrate not be allowed to drop below 5.0, since pH's below that range have a tendency to denature the protein. The pH may be adjusted with sodium hydroxide, potassium hydroxide, sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate or other equivalent bases.

The next step in the process is the diafiltration step. This diafiltration may be carried out using techniques well known in the art. In the diafiltration, the soy protein containing retentate produced via the ultrafiltration is rediluted with an aqueous solution and the admixture is brought into contact with the ultrafiltration membrane and subjected to a second ultrafiltration.

This diafiltration will typically be conducted in a batch manner. The soy protein containing retentate will be returned to reaction vessel (10). It will be rediluted with aqueous fluid. The volume of fluid may vary, but will typically be in the range of from about 50 to 120% of the volume used for the ultrafiltration and more preferably from 90 to 100%. For example if 10 liters of solution was used in the original ultrafiltration, then 5 to 12 liters will be used for the diafiltration. The diluted retentate will then be subjected to a second ultrafiltration in the same manner as described above. Alternatively, a recirculating ultrafiltration system may be used in which the retentate is pumped back directly to reaction vessel (10) and pumped back through the system. Detailed descriptions of such continuous diafiltration system may be found in "Ultrafiltration Handbook by Cheyans, supra.

At the conclusion of the diafiltration, the soy protein is typically processed so that it may be incorporated into other food products. The soy protein may be processed in the manner that is most optimal for the food product. Typically however the soy protein will be centrifuged, heat treated to reduce the chance for microbial contamination and dried.

The soy protein produced by the process above differs from that produced in the prior art. It has reduced levels of phytate. For example, soy flour (the typical starting material in the inventive process), contains 21-22 mg of phytate per gram of soy protein. Soy protein produced according to the invention will contain no more than about 5 mg of phytate and more preferably no more than about 1.6 to 1.7 mg of phytate. Soy flour typically contains about 7 to 8 gram of ribonucleic acids per kilogram of soy flour. Soy protein produced via the instant invention will contain no more than about 0.3 to about 0.4 grams of ribonucleic acids per kilogram of soy protein.

The soy proteins of this invention also have enhanced solubility compared with those of the prior art. Soy protein that is precipitated from soy flour via acidic conditions (i.e. a pH of less than 4.5) has a nitrogen solubility of 17 w/w % in water at room temperature. The soy proteins of this invention, typically have a solubility of at least 40 w/w % in water, at room temperature, at a pH of 7.0 and more typically about 55 w/w % under comparable conditions.

Soy protein that is precipitated from soy flour via acidic conditions (i.e., a pH of less than 4.5) has a surface hydrophobicity of 36.77 as determined by Hayakawa et al., supra. The soy proteins of this invention will have a hydrophobicity of no more than about 30 and more typically about 20.

The soy protein produced via the instant invention has superior emulsifying capacities. Soy protein that is precipitated from soy flour via acidic conditions (i.e. a pH of less than 4.5) has an emulsifying activity index of about 8.2 m²/gram and a stability index of about 27m²/gram. The soy protein produced according to this invention will have an emulsifying activity index of no greater than about 6m²/gram and a stability index of about 40 m²/gram.

The soy protein produced via this isolation process may be processed into food products and nutritional compositions as is typically known in the art. Due to the soy proteins superior emulsifying properties, it may be utilized in the production of enteral formula and especially medical foods. Since the soy protein has reduced levels of nucleic acids, phytate and isoflavones as well as enhanced emulsifying capacities, it will be especially suited for use in the production of infant formula.

An enteral formula of the present invention contains edible macronutrients, vitamins and minerals in amounts desired for a particular use. The amounts of such ingredients will vary depending on whether the formulation is intended for use with normal, healthy infants, children, or adults or subjects having specialized needs such as accompany certain pathological conditions (e.g., metabolic disorders). It will be understood by persons skilled in the art that the components utilized in an enteral formula of the present invention are of semi-purified or purified origin. By semi-purified or purified is meant a material which has been prepared by purification of a natural material or by synthesis. These techniques are well known in the art (See, e.g., Code of Federal Regulations for Food Ingredients and Food Processing; Recommended Dietary Allowances, 10th Ed., National Academy Press, Washington D.C., 1989).

In a preferred embodiment, a nutritional formulation is provided that is suitable for feeding infants. The formula comprises, in addition to the soy protein, macronutrients, vitamins and minerals in amounts designed to provide the daily nutritional requirements of infants. The macronutritional components include edible fats, carbohydrates and proteins. Exemplary edible fats are coconut oil, soy oil, sources of long chain polyunsaturated fatty acids, and mono- and diglycerides. Exemplary carbohydrates are glucose, edible lactose and hydrolyzed cornstarch. Typically, soy protein will be utilized in these formula, but if desired other protein sources such as whey or casein may be blended with the soy. These macronutrients would be added in the form of commonly accepted nutritional compounds in amounts equivalent to those present in human milk on an energy basis, i.e., on a per calorie basis.

The infant formula would preferably include the following vitamins and minerals: calcium, phosphorous, potassium, sodium, chloride, magnesium, manganese, iron, copper, zinc, selenium, iodine, and Vitamins A, E, D, C, and the B complex. Further nutritional guidelines for infant formula can be found in the Infant Formula Act, 21 USC section 350a.

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A more detailed description of infant formula and its preparation may be found in U.S. Pat. No. 5,021,045 which is hereby incorporated by reference. A typical infant formula will have the following composition 1) protein, said protein being of a concentration of between 10 and 25 grams per liter of formula; 2) fat, said fat being of a concentration of between 20 and 45 grams per liter; and 3) carbohydrates, said carbohydrates being of a concentration of between 60 and 110 grams per liter of formula. Preferably, the protein has as its source soy protein isolate alone, but sodium and calcium caseinates or a blend thereof may be incorporated if desired; said fat has as its source soy, coconut or corn oil, or another vegetable oil or a blend thereof; and said carbohydrates have as their source, sucrose, corn syrup, glucose polymers, or other carbohydrates, or a blend thereof.

The infant formula of this invention are preferably prepared using the following method. An appropriate quantity of protein is dispersed in sufficient water to solubilize it, thereby forming a protein solution. Typically this protein source would be soy protein isolate. A carbohydrate source such as one or more of corn syrup solids, maltodextrins, and sucrose is dissolved in water, thereby forming a carbohydrate solution. Appropriate minerals are dissolved in water, so as to form a mineral solution.

Once formed the solutions (protein, carbohydrate, and mineral) are combined in appropriate quantities with vegetable oils and oil soluble vitamins. The resulting solution is then heat processed and homogenized. Following processing, water soluble vitamins are added. The solution is then diluted with water to the appropriate caloric density, approximately 670-725 kcal per liter of formula for infants. The formula is then dispensed into containers and retorted to obtain commercial sterility. As prepared, the formula contains appropriate nutrients in compliance with the Infant Formula Act as of the date of this application. It should also be recognized that the unique formula of this invention could be prepared for use in powdered form or as a concentrated liquid. The powder can be prepared by spray drying the infant formula prepared as indicated above, and the formula can be reconstituted by rehydrating the concentrate.

Other advantages and embodiments of the invention will readily become apparent to those skilled in the art, based upon a review of the teachings of this document. The following examples are presented to further illustrate the invention, but they should not be viewed as limiting its disclosure in any manner. Any reference in this application to a numerical range should be construed as encompassing the range specified and any subset hereof. For example a range of 1 to 10 should also be construed as encompassing a range of 2-9, 3-6, 4-7, 8-9, 3-5, etc.

Examples 1

1000 grams of defatted soy flour was diluted in 20 liters of distilled water to give a 5% w/v solution to which 60 milliliters of the enzyme pectinase was added at a ratio of 0.3% v/v. The pectinase was obtained from Sigma Chemical Company of St. Louis, Mo. having a declared activity of 11.8 units/ milligram protein. (One unit will liberate 1.01 μ mole of galacturonic acid per min at pH 4.0 at 25° C.). The enzyme treatment was carried out in a steam jacketed kettle whose temperature was maintained between 37-42° C. for three hours. The solution was then pumped through a membrane system using three porous stainless-steel tubular microfiltration membranes (60 cm \times 1.57 cm i.d. per membrane). The membranes were supplied by Graver Separations, Inc., Seneca, S.C. The retentate was returned to

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the steam jacketed kettle and the permeate was collected as shown in FIG. 1. The permeate flux at the start of the microfiltration was 2.88 gallons/sq. ft./day at 950° F. The inlet pressure was 29.5 psi. Ten liters of permeate collected was labeled as the microfiltered permeate at which time the concentration of solids was 2x. The flux at the end of microfiltration was 0.81 gallons/sq.ft./ day at 102.2° F. and the inlet pressure was 40 psi. This was designated as the end of microfiltration. Diafiltration that follows microfiltration does not result in any further concentration of solids. Ten liters of water equal to the volume of microfiltered permeate collected as added back to the kettle and filtration was allowed to continue through the membranes until ten liters of diafiltered permeate was collected. The permeate flux immediately after the addition of ten liters of water (i.e., at the start of diafiltration) was 2.00 gallons/sq.ft./day at 86° F. and the inlet pressure was 34 psi. At the end of diafiltration the permeate flux was 0.96 gallons/sq. ft./day at 105.80° F. and the inlet pressure was 44 psi. The pump was shut off after diafiltration and the retentate was collected for further processing. The pH of the permeate (6.23) was adjusted to pH 9.0 with few drops of 50% sodium hydroxide and stirred continuously to increase protein solubility. The solution was then centrifuged at 2000 \times g for 20 minutes to remove the insoluble solids. The supernatant was the freeze dried to obtain a flaky powder that was used for further analysis.

Example 2

1000 grams of defatted soy flour was diluted in 20 liters of distilled water to give a 5% w/v solution to which 180 milliliter of the enzyme Crystalzyme 100XL was added at a ratio of 0.9% v/v. The crystalzyme was obtained from Valley Research, Inc., South Bend, IN having a declared activity of 110,000 Apple Juice Depectinising Units (AJDU) units/gram protein. The enzyme treatment was carried out in a steam jacketed kettle whose temperature was maintained between 37-42° C. for three hours. The solution was then pumped through a membrane system using three porous stainless-steel tubular microfiltration membranes (60 cm \times 1.57 cm i.d. per membrane). The membranes were supplied by Graver Separations, Inc., Seneca, S.C. The retentate was returned to the steam jacketed kettle and the permeate was collected as shown in FIG. 1. The permeate flux at the start of the microfiltration was 4.32 gallons/sq.ft./ day at 98.6° F. The inlet pressure was 25 psi. Ten liters of permeate collected was labeled as the microfiltered permeate at which time the concentration of solids was 2x. The flux at the end of micro filtration was 0.72 gallons/sq.ft./day at 118.40° C. and the inlet pressure was 30 psi. This was designated as the end of microfiltration. Diafiltration that follows microfiltration does not result in any further concentration of solids. Ten liters of water equal to the volume of microfiltered permeate collected was added back to the kettle and filtration was allowed to continue through the membranes until ten liters of diafiltered permeate was collected. The permeate flux immediately after the addition of 10 liters of water (i.e., at the start of diafiltration) was 2.16 gallons/sq.ft./day at 122° F. and the inlet pressure was 40 psi. At the end of diafiltration the permeate flux was 1.20 gallons/sq.ft./day at 122° F. and the inlet pressure was 30 psi. The pump was shut off after diafiltration and the retentate was collected from the kettle for further processing. The pH of the permeate (6.20) was adjusted to pH 9.0 with few drops of 50% sodium hydroxide and stirred continuously to increase protein solubility. The solution was then centrifuged at 2000 \times g for 20 minutes to remove the insoluble solids. The supernatant was then freeze dried to obtain a flaky powder that was used for further analysis.

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Example 3

500 grams of defatted soy flour was diluted in 10 liters of distilled water to give a 5% w/v solution to which no enzyme was added and this was treated as control. The enzyme treatment was stirred in a steam jacketed kettle whose temperature was maintained between 37–420° C. for three hours. The solution was then pumped through a membrane system using three porous stainless-steel tubular microfiltration membranes (60 cm×1.57 cm i.d. per membrane). The membranes were supplied by Graver Separations, Inc., Seneca, S.C. The retentate was returned to the steam jacketed kettle and the permeate was collected as shown in FIG. 1. The permeate flux at the start of the microfiltration was 3.16 gallons/sq.ft./day at 950° F. The inlet pressure was 14 psi. Five liters of permeate collected was labeled as the microfiltered permeate at which time the concentration of solids was 2x. The flux at the end of microfiltration was 0.93 gallons sq. ft./day at 102.2° F. and the inlet pressure was 20 psi. This was designated as the end of microfiltration. Diafiltration that follows microfiltration does not result in any further concentration of solids. Five liters of water equal to the volume of microfiltered permeate collected was added back to the kettle and filtration was allowed to continue through the membranes until five liters of diafiltered permeate was collected. The permeate flux immediately after the addition of five liters of water (i.e., at the start of diafiltration) was 2.16 gallons/sq.ft./day at 86° F. and the inlet pressure was 35 psi. At the end of diafiltration the permeate flux was 0.77 gallons/sq.ft./day at 105.8° F. and the inlet pressure was 13 psi. The pump was shut off after diafiltration and the retentate was collected for further processing. The pH of the permeate (6.20) was adjusted to pH 9.0 with few drops of 50% sodium hydroxide and stirred continuously to increase protein solubility. The solution was then centrifuged at 2000[m]g for 20 minutes to remove the insoluble solids. The supernatant was then freeze dried to obtain a flaky powder that was used for further analysis.

Example 4

The freeze dried flaky powder obtained after the ultrafiltration used to concentrate the soy proteins from defatted soy flour was pulverized to a fine powder using a mortar and pestle. The freeze dried retentate from the enzyme treatments and membrane processing, soy flour and permeate collected were analyzed for protein. The protein content was calculated using a conversion factor of 6.25 to convert the nitrogen content estimated by the Microkjeldahl analysis as described in AOAC Section 47.021, 1975 and are presented in Table 1.

TABLE 1

Sample	Protein Content (%)
Soy Flour	51.2
Diafiltered Retentate	56.2
Pectinase Retentate	76.7
Crystalzyme Retentate	78.5
Permeate	<0.5

As seen in Table 1 the protein content of the diafiltered retentate was only 56.2% but adjusting the pH to 9.0 resulted in a protein content of 76.7% and 78.5% respectively. This example therefore suggest that increasing the pH is necessary to enhance the solubility and recovery of soy proteins. Also, the permeate contained less than 0.5% suggesting that

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the nitrogen may be non protein nitrogen released from nucleic acids and that the rejection of the soy bean proteins by the membranes during microfiltration and diafiltered retentate was nearly 100%. From the results of Table 1 it is clear that the soy proteins from soy flour are concentrates based on the definition that a soy protein concentrate should contain at least 70% protein on a dry weight basis.

Example 5

HPLC Gel filtration was used to determine the molecular weight profile of soy flour, permeate and retentate samples. The standard proteins used for molecular weight comparison included apoferritin (MW 443,000), β amylase (MW 200,000), bovine serum albumin (MW 66,000), ovalbumin (MW 43,000) α lactalbumin (MW 14,200) and tryptophan (MW 204). The retention times of the standards are given in Table 2.

TABLE 2

Standard Protein	Molecular Weight (Daltons)	Retention Time (min)
Apoferritin	443,000	28.3
	200,000	29.85
β amylase	66,000	32.36
Bovine serum albumin		
Ovalbumin	43,000	33.72
	14,200	36.69
α Lactalbumin	204	51.02
DL Tryptophan		

The HPLC profiles of proteins from soy flour, diafiltered retentate and permeate are shown in FIG. 2. The retention times for peaks in the soy flour and retentate were the same but some changes in peak areas were observed. This indicated that the major soy proteins were intact in the retentate. The first peaks in the permeate had a retention time around 40 minutes which corresponds to a molecular weight of 6500 daltons. This means that proteins with molecular weights greater than 6500 were retained by the membrane whereas proteins with molecular weights less than 6500 passed through the membrane into the permeate.

Example 6

The compositional analysis constituting of protein, carbohydrate, ash and moisture soy flour, commercial soy protein isolate and the two enzyme treated membrane soy concentrates (MSC) was determined and the results presented in Table 2.

TABLE 2

Sample	% Protein	% Carbohydrate	% Ash	% Moisture
Soy Flour	51.2	15.2	6.2	7.2
Supro 1610	86.7	1.7	4.3	5.2
MSC (Sigma)	76.7	8.9	5.3	5.4
MSC (Crystalzyme)	78.5	5.7	4.9	6.9

The results of this example suggest that processing with enzymes and microfiltration/diafiltration can produce a concentrated soy protein product approaching the identity of current soy protein isolates without using acid precipitation.

Example 7

Several compounds have been identified to contribute to soy flavor and odor that have been characterized as green,

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grassy, bitter and beany. The typical flavor of soy has before been a critical factor and has limited its extensive use in the United States and Europe. The volatile compounds from soy flour, microfiltered retentate and diafiltered retentate was extracted in 50% methanol and subjected to gas chromatographic analysis. The permeate samples did not need extraction prior to gas chromatography. FIG. 3 shows that the soy flour and permeate had similar profiles with major peaks around 6, 10, and 21 minutes. FIG. 4 shows that the diafiltered retentate had smaller peaks and reduced area under the peaks, as compared to soy flour, representing a reduction of flavor. FIG. 5 shows the comparison of the GC profiles of soy flour, filtered retentate and diafiltered retentate and it was apparent that microfiltration alone resulted in only a slight reduction in the volatile components. FIG. 6 shows the comparison of the GC profiles of soy flour, diafiltered retentate and permeate and it was apparent that that volatiles removed during microfiltration and diafiltration were indeed being lost in the permeate. Statistical analysis ($p < 0.001$) on the peak areas of the GC profiles showed a significant difference between that of the microfiltered and the diafiltered retentate. The results of this example suggest that microfiltration alone was not effective in removing the flavor from soy flour and in fact diafiltration was necessary to significantly reduce the volatile components in soy flour and that the flavor reduction after diafiltration was nearly 90% based on the mean peak areas in the profiles.

Example 8

While Example 7 based GC analysis suggest the effective removal of flavor compounds after microfiltration and diafiltration, the importance of sensory evaluation cannot be stressed enough. Sensory evaluations for aroma and flavor were completed for soy flour, commercial soy isolate and concentrate made with pectinase and crystalzyme. The responses for first detected aroma included beany, corn meal, musty and toasted while the responses for the first detected flavor included beany, bitter, chalky and astringent. The results of this sensory evaluation are presented in Table 3.

TABLE 3

Sample	Mean Aroma	Mean Flavor
Soy Flour	56.7 ^a	50.2 ^d
Supro 1610	53.1 ^{ab}	50.8 ^d
MSC (Pectinase)	45.8 ^b	35.7 ^c
MSC (Crystalzyme)	29.6 ^c	35.5 ^c

Means with the same letter are not significantly different ($p < 0.05$).

From the scores in Table 3 it is clear that the general aroma and flavor differences among soy flour, soy isolate and the two membrane concentrates were noticeable to untrained human subjects. Based on this information, a more detailed descriptive sensory evaluation of soy flour, commercial soy isolate and the membrane soy concentrate processed with crystalzyme was undertaken using trained human subjects. The panelists were chosen based on their stability to identify the four basis tastes of sweet, sour, salty and bitter. The panelists were then asked to evaluate the aroma and flavor using descriptors which had been gathered from literature and preliminary discussions with the panelists. The use of standard samples helped to achieve agreement among the panelists on the definitions and relative importance of each descriptor. The chosen aroma descriptors included wheat flour like, raw soybean like, green bean like

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and toasted grain like. Flavor by mouth descriptors included wheat flour like, raw soybean like, green bean like, toasted grain like, sweet and bitter. FIG. 7 shows that the membrane soy concentrate was evaluated to possess a 'toasted grain' aroma and flavor while FIG. 8 shows that the membrane soy concentrate possessed the least 'soy bean' taste. This example therefore suggests that the absence of soy volatiles believed to contribute to the typical soybean aroma and flavor are perceived by both trained and untrained human panelists.

Example 9

Solutions of varying solids concentration in three different batches were used in the production of membrane soy concentrate so as to be able to optimize the microfiltration and diafiltration process outlined for the concentration of soy proteins. Batch I used 9.9 pounds of defatted soy flour diluted in 198 pounds of water so as to give a concentration of 5% w/w in a steam jacketed kettle to which 810 milliliters of the enzyme Crystalzyme 100XL was added at a ratio of 0.9% v/v. The crystalzyme was obtained from Valley Research, Inc., South Bend, IN having a declared activity of 110,000 AJDU units/gram protein. The enzyme treatment was carried out in a steam jacketed kettle whose temperature was maintained between 37–420° C. for three hours. The solution was then pumped through a membrane system using three porous stainless-steel tubular microfiltration membranes (60 inches×0.72 inches i.d. per membrane). Two such modules were used in parallel connection. In addition two single pass tubular microfiltration membranes (60 inches×1.25 inches i.d. per membrane) were also used in conjunction so as to increase the surface area and capacity. The membranes were supplied by Graver Separations, Inc., Seneca, S.C. The retentate was returned to the steam jacketed kettle and the permeate was collected as shown in FIG. 1. The permeate flux at the start of the microfiltration process was 47.93 gallons/sq.ft./day at 104° F. The inlet pressure was 56 psi and the outlet pressure was 34 psi. 90 pounds of water was collected at the permeate end to mark the end of microfiltration. The permeate flux at the end of microfiltration was 36.20 gallons/sq.ft./day at 119° F. The inlet pressure was 74 psi and the outlet pressure was 50 psi. Diafiltration was continued as a continuous feed and bleed process wherein 100 pounds of distilled water was added in three batches of 35 pounds, 35 pounds and 30 pounds respectively. The permeate flux at the start of diafiltration was 30.93 gallons/sq.ft./day at 112° F. The inlet and outlet pressures were 74 psi and 50 psi. The collection of 100 pounds permeate marked the end of diafiltration. The permeate flux was 27.12 gallons/sq.ft./day at 118° F. The inlet and outlet pressures were 76 psi and 52 psi respectively. The pump was shut off after diafiltration and the retentate was collected for further processing. The pH of the retentate (6.20) was adjusted to pH 9.0 with few drops of 50% sodium hydroxide and stirred continuously to increase protein solubility. The supernatant was then freeze dried to obtain a flaky powder that was used for further analysis.

Batch II used 19.8 pounds of defatted soy flour diluted in 198 pounds of water so as to give a concentration of 10% w/w in a steam jacketed kettle to which 810 milliliters of the enzyme Crystalzyme 100XL was added at a ratio of 0.9% v/v. The crystalzyme was obtained from Valley Research, Inc., South Bend, Ind. having a declared activity of 110,000 AJDU units/gram protein. The enzyme treatment was carried out in a steam jacketed kettle whose temperature was maintained between 37–420° C. for three hours. The solution was then pumped through a membrane system using

three porous stainless-steel tubular microfiltration membranes (60 inches \times 1.25 inches i.d. per membrane) were also used in conjunction so as to increase the surface area and capacity. The membranes were supplied by Graver Separations, Inc., Seneca, S.C. The retentate was returned to the steam jacketed kettle and the permeate was collected as shown in FIG. 1. The permeate flux at the start of the microfiltration process was 45.77 gallons/sq.ft./day at 105° F. The inlet pressure was 46 psi and the outlet pressure was 28 psi. 90 pounds of water was collected at the permeate end to mark the end of microfiltration. The permeate flux at the end of microfiltration was 24.18 gallons/sq.ft./day at 119° F. The inlet pressure was 55 psi and the outlet pressure was 30 psi. Diafiltration was continued as a continuous feed and bleed process wherein 100 pounds of distilled water was added in three batches of 35 pounds, 35 pounds and 30 pounds respectively. The permeate flux at the start of diafiltration was 16.78 gallons/sq.ft./day at 110° F. The inlet and outlet pressures were 55 psi and 30 psi. The collection of 100 pounds permeate marked the end of diafiltration. The permeate flux was 11.69 gallons/sq.ft./day at 119° F. The inlet and outlet pressures were 70 psi and 46 psi respectively. The pump was shut off after diafiltration and the retentate was collected for further processing. The pH of the retentate (6.25) was adjusted to pH 9.0 with few drops of 50% sodium hydroxide and stirred continuously to increase protein solubility. The solution was then centrifuged at 2000 \times g for 20 minutes to remove the insoluble solids. The supernatant was then freeze dried to obtain a flaky powder that was used for further analysis.

Batch III used 22.6 pounds of defatted soy flour diluted in 180.8 pounds of water so as to give a concentration of 12.5% w/w in a steam jacketed kettle to which 739.6 milliliters of the enzyme Crystzyme 100XL was added at a ratio of 0.9% v/v. The crystallzyme was obtained from Valley Research, Inc., South Bend, Ind. having a declared activity of 110,000 AJDU units/gram protein. The enzyme treatment was carried out in a steam jacketed kettle whose temperature was maintained between 37–420° C. for three hours. The solution was the pumped through a membrane system using three porous stainless-steel tubular microfiltration membranes (60 inches \times 0.72 inches i.d. per membrane). Two such modules were used in parallel connection. In addition two single pass tubular microfiltration membranes (60 inches \times 1.25 inches i.d. per membrane) were also used in conjunction so as to increase the surface area and capacity. The membranes were supplied by Graver Separations, Inc., Seneca, S.C. The retentate was returned to the steam jacketed kettle and the permeate was collected as shown in FIG. 1. The permeate flux at the start of the microfiltration process was 29.51 gallons/sq.ft./day at 106° F. The inlet pressure was 80 psi and the outlet pressure was 43 psi. 90 pounds of water was collected at the permeate end to mark the end of microfiltration. The permeate flux at the end of microfiltration was 18.75 gallons/sq.ft./day at 116° F. The inlet pressure was 81 psi and the outlet pressure was 53 psi. Diafiltration was continued as a continuous feed and bleed process wherein 90 pounds of distilled water was added in three batches of 30 pounds each. The permeate flux at the start of diafiltration was 16.44 gallons/sq.ft./day at 109° F. The inlet and outlet pressures were 78 psi and 50 psi. The collection of 90 pounds permeate marked the end of diafiltration. The permeate flux was 5.86 gallons/sq.ft./day at 1180° F. The inlet and outlet pressures were 80 psi and 52 psi respectively. The pump was shut off after diafiltration and the retentate was collected for further processing. The pH of the retentate (6.00) was adjusted to pH 9.0 with few drops of 50% sodium

hydroxide and stirred continuously to increase protein solubility. The solution was the centrifuged at 2000 \times g for 20 minutes to remove the insoluble solids. The supernatant was then freeze dried to obtain a flaky powder that was used for further analysis.

Table 3 shows the compositional analysis constituting of protein, carbohydrate, ash and moisture of soy concentrate produced in the three batches. Table 4 an FIG. 9 show the effect of solids concentration on the flux, processing time and permeability.

TABLE 3

Batch	% Protein	% Carbohydrate	% Ash
One	78.3*	4.01*	4.73*
Two	78.2*	4.77*	4.89*
Three	76.1*	3.20*	7.89*

Means with the same letter are not significantly different ($p < 0.05$).

TABLE 4.

Initial Solids Concentration	Process Status	Time (min)	Flux (GFD)	Permeability*
5%	Initial	16.52	47.93	0.26
	End of Microfiltration	49.95	36.20	0.14
	Start of Diafiltration	53.05	30.93	0.12
	End of Diafiltration	112.17	27.12	0.10
10%	Initial	19.39	45.77	0.30
	End of Microfiltration	74.68	24.18	0.14
	Start of Diafiltration	80.45	16.78	0.10
	End of Diafiltration	233.18	11.69	0.05
12.5%	Initial	17.39	29.51	0.10
	End of Microfiltration	68.88	18.75	0.07
	Start of Diafiltration	74.77	16.44	0.06
	End of Diafiltration	301.25	5.86	0.02

*Permeability = Flux (LMH)/Pressure (kPa)

This example suggest that doubling the initial solids concentration is time effective with a marginal decrease in flux and permeability. However, any further increase in the solids concentration is associated with a steep decrease in flux and permeability and a considerable increase in processing time. Also, doubling the solids concentration does not alter the composition of the membrane soy concentrate produced.

Example 10

19.8 pounds of defatted soy flour was diluted in 198 pounds of distilled water to give a 10% w/w solution to which 810 milliliters of the enzyme Crystzyme 100XL was added at a ratio of 0.9% v/v. The crystallzyme was obtained from Valley Research, Inc., South Bend, Ind. having a declared activity of 110,000 AJDU units/gram protein. The enzyme treatment was carried out in a steam jacketed kettle whose temperature was maintained between 37–42° C. for three hours. The solution was then pumped through a membrane system using three porous stainless-steel tubular microfiltration membranes (60 inches \times 0.72 inches i.d. per membrane). Two such modules were used in parallel connection. In addition two single pass tubular microfiltration membranes (60 inches \times 1.25 inches i.d. per membrane) were also used in conjunction so as to increase the surface area and capacity. The membranes were supplied by Graver Separations, Inc., Seneca, S.C. The retentate was returned to the steam jacketed kettle and the permeate was collected as shown in FIG. 1. 90 pounds of water was collected at the permeate end to mark the end of microfiltration. Diafiltration was continued as a continuous feed and bleed process

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wherein 100 pounds of distilled water was added in three batches of 35 pounds, 35 pounds and 30 pounds respectively. The pump was shut off after diafiltration and the retentate was collected for further processing. The pH of the retentate was adjusted to pH 9.0 with a few drops of 50% sodium hydroxide and stirred continuously to increase protein solubility. The solution was then centrifuged at 2000xg for 20 minutes to remove the insoluble solids. The supernatant was the freeze dried to obtain a flaky powder that was used for further analysis.

Five batches as outlined above were processed on different days and the results of the compositional analysis regarding protein, carbohydrate and ash are presented in Table 6.

TABLE 6

Replicate	% Protein	% Carbohydrate	% Ash
One	78.3 ^a	4.01 ^a	4.73 ^a
Two	78.9 ^a	3.67 ^a	4.86 ^a
Three	78.21 ^a	3.28 ^a	4.92 ^a
Four	80.56 ^a	5.78 ^b	5.67 ^b
Five	81.08 ^a	5.69 ^b	5.60 ^a

Means with the same letter are not significantly different ($p < 0.05$).

The example suggest that pilot plant scale processing consistently resulted in a membrane soy concentrate with identical protein composition. This strongly emphasized the reproducibility of the ultrafiltration system consisting of microfiltration and diafiltration in the production of membrane soy concentrate.

Example 11

Yields and recovery form an important characteristic while establishing the feasibility of a process. The theoretical yields were calculated based on the protein content of the soy flour using a mass balance ratio between the protein content and the mass of the different processing fractions which include microfiltered permeate, diafiltered permeate and the retentate. The percent distribution of protein in the different fractions of the five batches processed with 1.0% w/w solids concentration as outlined in Example 9 are calculated and presented in Table 7.

TABLE 7

Replicate	Microfiltered Permeate	Diafiltered Permeate	Membrane Soy Concentrate
One	15.66	12.56	71.78
Two	12.33	9.92	77.75
Three	10.9	8.46	80.64
Four	13.23	5.26	81.51
Five	7.3	5.38	87.32

This example suggests that the yield of protein as the membrane soy concentrate is 80% on an average. The yield reported in literature for soy protein isolates was 60% of the protein. Therefore, this process described here would significantly increase protein yields over current processes.

Example 12

Physical and chemical properties that affect the behavior of proteins in food systems during storage, processing, preparation and consumption are often referred to as functionality. Some examples of functional properties include solubility, hydration, emulsifying properties an surface hydrophobicity.

22

The approximate water hydration capacity is defined as grams of water bound per gram of dry protein and describes water-protein interactions. Information on the hydration capacity is important since water is an important constituent of all food systems. The water hydration capacity of soy flour, membrane soy concentrate and commercial isolate (Supra 1610) was determined by the method outlined by Quinn and Paton (1979), supra. Surface hydrophobicity is another water-protein interaction that defines that portion of the non-polar surface of the protein that makes contact with the surrounding bulk water. Surface hydrophobicity of the three soy protein samples were evaluated by the method outlined by Hyakawa and Nagai (1985), supra. The results of water hydration capacity an surface hydrophobicity and presented in Table 8.

TABLE 8

Sample	Water Hydration Capacity	Surface Hydrophobicity
Soy Flour	2.35 ^a	10.52
Membrane Soy Concentrate	2.61 ^a	20.65
Supra 1610	5.64	36.77

Means with the same letter are not significantly different ($p < 0.05$).

Insoluble proteins have very limited use in foods. Nitrogen solubility can be assumed to be reflective of protein solubility. Protein solubility is known to influence functional properties such as foaming, gelation and emulsification. Solubility is influenced by several conditions, pH being an important one. The nitrogen solubility of soy flour, membrane soy concentrate and commercial soy isolate was determined in the pH range between 3.0 and 10.0 by the method outlined by Bera and Mukherjee (1989), supra and is presented FIG. 10.

Ultrafiltration in the case of the membrane soy concentrate does not seem to have disrupted the structures so as to bring about an increase in the hydration capacity. Acid modification in the commercial soy isolate seems to have contributed to a greater water hydration capacity and seems to have unfolded the protein molecule to a large extent resulting in increased exposure of hydrophobic groups to the probe. Statistical analysis of the nitrogen solubility means indicated that the isolate had the least solubility, irrespective of the influence of pH. Soy flour showed the highest solubility with the membrane soy concentrate following a lesser but similar pattern to that of soy flour. This example suggest that membrane processing used to concentrate soy proteins seems to leave the protein molecule intact with little denaturation.

Example 13

Emulsions are dispersions of one liquid in another and are of two types viz., oil in water e.g., milk and milk products and water in oil e.g. butter and margarine. Proteins are the emulsifiers of choice for oil in water emulsions because they are edible and surface active. Emulsifiers are evaluated both in terms of emulsifying activity and emulsifying stability because an emulsifier is important to for an emulsion and also stabilize the emulsion after it has been formed. The emulsifying properties of soy flour, membrane soy concentrate and commercial soy isolate were evaluated by the method of Pearce and Kinsella (1978), supra and compared to that of an established protein emulsifier like bovine serum albumin. While there are several methods to evaluate the emulsifying properties, the method used here was based on the determination of the emulsifying activity index which

relates the turbidity of the emulsion to the interfacial area of an emulsion and is expressed in m²/g. This method may not be completely accurate but it can be effectively used for qualitative comparison of emulsifying activities of different proteins. The results on the emulsifying activity and emulsion stability of the different soy proteins and bovine serum albumin are presently in FIG. 11. Statistical analysis on the emulsifying activity indices reveal a difference ($p < 0.05$) among the three soy proteins with the flour exhibiting the highest index. This higher index may be attributed to higher solubility observed in soy flour. Data on the stability of emulsions formed as a function of time reveal that the membrane soy concentrate exhibited the highest index when compared to soy flour and soy isolate. This example suggest that the concentration of the proteins by ultrafiltration does not alter the emulsifying properties of the soy proteins when compared to that of native proteins in soy flour.

Example 14

Protein forms an integral constituent of the diet and quality is critical to support growth and development especially during the growing years of infancy and adolescence. The quality of proteins can be evaluated by several biological, chemical and enzymatic methods and is related to its amino acid composition. The protein quality of membrane soy concentrate, commercial soy isolate and casein was evaluated by comparing each of their amino acid compositions with the essential amino acid pattern recommended by FAO/WHO/UNU. 1985. Energy and protein requirements. Report of a Joint FAO/WHO/UNU expert consultation. World Health Organization Technical Rep. Ser. 724, WHO, Geneva for infants and the results are presented in Table 9.

TABLE 9

Essential Amino Acid*	RDA**	Casein	Membrane Soy Concentrate	Commercial Soy Isolate
Histidine	26	28.49	27.13	26.10
Isoleucine	46	50.20	49.08	46.46
Leucine	93	90.97	79.06	78.63
Lysine	66	71.62	54.46	63.03
Methionine + Cysteine	42	32.91	27.43	26.88
Phenylalanine + Tyrosine	72	102.56	92.35	89.46
Threonine	43	43.52	42.54	40.51
Tryptophan	17	9.53	12.08	11.92
Valine	55	60.61	50.35	53.72

*All values expressed as mg/gprotein.

**Recommended Dietary Allowances.

The essential amino acid profile of the membrane soy concentrate is not that different from the commercial soy isolate in comparison. The chemical score for each of the essential amino acids was calculated as follows:

$$\text{Chemical Score} = \frac{\text{mg amino acid/g test protein}}{\text{mg amino acid/reference protein}} \times 100$$

Based on the chemical scores calculated for the essential amino acid, the membrane soy concentrate when compared to casein is seen to lack marginally (2-5%) in isoleucine, threonine and histidine 14-15% less in leucine and valine with a significant lack in tyrosine (27%) and methionine (50%). This example suggests that the low methionine content of membrane soy concentrate is reflective of the limiting amino acids in soy flour from which the soy

concentrate is processed. It seems as if membrane processing does not alter the amino acid pattern of the soy protein after concentration.

Example 15

The purpose of this example is to demonstrate that the process of this invention will reduce isoflavone levels in soy protein. Twenty five (25) pounds of soy protein concentrate was produced in a manner analogous to that of Example 1. The isoflavone content of this material was determined using the method of Wang and Murphy, supra. For comparative purposes, soy protein isolate was purchased from Protein Technologies Inc. of St. Louis, Mo. Ten different lots of PTI material were tested and their results were averaged. The obtained results are depicted below in Table 10 (all values are expressed as mg/kg of protein on a dry weight basis).

TABLE 10

Isoflavone % reduction	Soy Concentrate of Process	Control (PTI Isolate)
Daidzin (total) 71	146.11	498.5
Glycitin (total) 82	18.57	103.4
Genistin (total) 78	245.34	1,115
Grand Total:	409.2	1,716.9

Example 16

Using methodology similar to that of Example 1, Twenty five (25) pounds of soy protein concentrate was produced. The phytate level of this material was evaluated by the method of McChance and Widdewson, supra. The soy protein concentrate had a phytate level of 0.026 w/w %. By contrast soy flour will typically have a phytate level of 2 to 3 w/w %.

We claim:

1. A process for the removal of isoflavones, phytate, and nucleic acids from soy protein comprising:

- a) contacting a source of soy protein with one or more enzymes possessing nuclease and phytase activity for a sufficient period of time to allow said enzymes to react with said source of soy protein;
- b) subjecting the soy protein source of step a) to ultrafiltration by passing said soy protein source through a metallic oxide ultrafiltration membrane at sufficient pressures, to maintain a permeability of the ultrafiltration membrane in the range of about 0.04 to 0.3 gallons/square feet/day (gfd), and for a sufficient period of time to create a retentate, containing soy protein;
- c) diluting said retentate with an aqueous solution to form a diluted retentate and passing said diluted retentate through a metallic oxide ultrafiltration membrane, and;
- d) collecting the diluted retentate, from which isoflavones, phytate, and nucleic acids have been removed.

2. The process according to claim 1 in which said enzyme is pectinase.

3. The process according to claim 1 in which said enzymatic treatment is carried out for a period of time of at least 3 hours.

4. The process according to claim 1 in which said source of soy protein is present in the enzymatic treatment at a level of about 5% w/w to about 12.5% w/w.

5. The process according to claim 1 in which said ultrafiltration membrane retains molecules having a molecular weight of 6500 daltons or greater.

6. The process according to claim 1 in which said ultrafiltration membrane has an initial permeability to water of about 0.55 to about 0.58 gfd.

relates the turbidity of the emulsion to the interfacial area of an emulsion and is expressed in m^2/g . This method may not be completely accurate but it can be effectively used for qualitative comparison of emulsifying activities of different proteins. The results on the emulsifying activity and emulsion stability of the different soy proteins and bovine serum albumin are presently in FIG. 11. Statistical analysis on the emulsifying activity indices reveal a difference ($p < 0.05$) among the three soy proteins with the flour exhibiting the highest index. This higher index may be attributed to higher solubility observed in soy flour. Data on the stability of emulsions formed as a function of time reveal that the membrane soy concentrate exhibited the highest index when compared to soy flour and soy isolate. This example suggests that the concentration of the proteins by ultrafiltration does not alter the emulsifying properties of the soy proteins when compared to that of native proteins in soy flour.

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We claim:

1. A process for the removal of isoflavones, phytate, and nucleic acids from soy protein comprising:

- a) contacting a source of soy protein with one or more enzymes possessing nuclease and phytase activity for a sufficient period of time to allow said enzymes to react with said source of soy protein;
- b) subjecting the soy protein source of step a) to ultrafiltration by passing said soy protein source through a metallic oxide ultrafiltration membrane at sufficient pressures, to maintain a permeability of the ultrafiltration membrane in the range of about 0.04 to 0.3 gallons/square feet/day (gfd), and for a sufficient period of time to create a retentate, containing soy protein;
- c) diluting said retentate with an aqueous solution to form a diluted retentate and passing said diluted retentate through a metallic oxide ultrafiltration membrane, and;
- d) collecting the diluted retentate, from which isoflavones, phytate, and nucleic acids have been removed.

2. The process according to claim 1 in which said enzyme is pectinase.

3. The process according to claim 1 in which said enzymatic treatment is carried out for a period of time of at least 3 hours.

4. The process according to claim 1 in which said source of soy protein is present in the enzymatic treatment at a level of about 5% w/w to about 12.5% w/w.

5. The process according to claim 1 in which said ultrafiltration membrane retains molecules having a molecular weight of 6500 daltons or greater.

6. The process according to claim 1 in which said ultrafiltration membrane has an initial permeability to water of about 0.55 to about 0.58 gfd.

APPENDIX H

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Examiner : Deborah K. Ware
Group Art Unit: : 1651
Applicants : Wong et al.
Serial No. : 09/912,494
Filed : July 24, 2001
For : ULTRAPURE PROTEIN MATERIAL

Hon. Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION UNDER 37 CFR §1.131

Theodore M. Wong declares as follows:

1. I am an inventor of the subject matter of the above identified patent application—U.S. Patent Application Serial No. 09/912,494.
2. I have been an employee of Solae, LLC (formerly Protein Technologies International, Inc.), the assignee of the present invention as claimed in the above identified patent application, since August 1985.
3. In a Final Office Action dated July 1, 2003 pending claims 79-86 were rejected under 35 U.S.C. §102(e) as anticipated by, or in the alternative under 35 U.S.C. §103(a) as obvious over, U.S. Patent No. 6,313,273 to Thomas et al. Further, claims 79 and 86 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,313,273 to Thomas et al. in view of U.S. Patent No. 6,313,328 to Ulrich et al. U.S. Patent No. 6,313,273 to Thomas et al was filed in the United States Patent Office on August 25, 1999.
4. The present application—U.S. Serial No. 09/912,494—was filed in the United States Patent Office on July 24, 2001 as a continuation-in-part application of application U.S. Serial No. 08/996,976 filed December 23, 1997. Support for the limitation in claim 79 of a soy protein material “containing at most 4000 mg/kg

ribonucleic acids and being substantially devoid of ribonucleic enzymes” was added to the original specification of U.S. Serial No. 08/996,976 when the present application was filed on July 24, 2001. Likewise, the support for the limitation of claim 81 of a soy protein material containing “less than 2000 mg/kg of ribonucleic acids” and for the limitation of claim 82 of a soy protein material containing less than 1500 mg/kg of ribonucleic acids” was added to the original specification of U.S. Serial No. 08/996,976 in filing the present application.

5. Prior to August 25, 1999 I conceived the idea of a soy protein material containing at most 4000 mg/kg of ribonucleic acids, less than 2000 mg/kg of ribonucleic acids, and less than 1500 mg/kg of ribonucleic acids, as shown by paragraph 7 below. The conception occurred within the United States.
6. Prior to August 25, 1999 I reduced to practice a soy protein material containing at most 4000 mg/kg of ribonucleic acids; a soy protein material containing less than 2000 mg/kg of ribonucleic acids; and a soy protein material containing less than 1500 mg/kg of nucleic acids as shown by paragraph 7 below. The reduction to practice occurred within the United States.
7. Prior to August 25, 1999 an experiment was conducted in the United States under my direction and control to measure the amount of degradation of ribonucleic acids in a soy protein material by an acid phosphatase enzyme and by a phytase enzyme. Three samples, among others, of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample (“Control”), the second sample was dosed with an acid phosphatase enzyme preparation (Finase) having an enzyme activity of 1400 KPU per Kg curd solids (“Acid Phosphatase”) and the third sample was dosed with NATUPHOS® phytase enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids (“Natuphos”). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then treated with bacterial alkaline phosphatase to degrade monomeric nucleotides to monomeric nucleosides and then the free monomeric

nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provided a measure of the amount of monomeric nucleotides and monomeric nucleosides present in the sample ("Monomerics"). Another sample of each of the three samples was treated with a nuclease to hydrolyze polymeric ribonucleic acids to monomeric nucleotides, then was treated with pyrophosphatase to hydrolyze ribonucleoside containing adducts to monomeric nucleotides, then was treated with bacterial alkaline phosphatase to hydrolyze the monomeric nucleotides to free monomeric nucleosides, and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provided a measure of the total amount of ribonucleoside containing compounds, both polymeric and monomeric, since the nuclease and pyrophosphatase treatments degraded the polymeric ribonucleoside-containing compounds to monomeric nucleotides, which were then subsequently degraded to monomeric nucleosides with bacterial alkaline phosphatase ("Total Nucleoside"). The resulting Monomeric and Total Nucleoside contents by weight of nucleosides in mg/kg of soy protein material for each treated sample and the control are shown in Table 1.

TABLE 1

Sample	Uridine	Cytidine	Guanosine	Adenosine	Total
Control					
--Monomerics _c	172	121	237	127	657
--Total Nucleoside _c	4302	5320	6711	5886	22219
Acid Phosphatase					
--Monomerics _{ap}	5188	6886	7175	2204	21453
--Total Nucleoside _{ap}	5281	7015	7599	2495	22390
Natuphos (phytase)					
--Monomerics _p	231	128	240	184	783
--Total Nucleoside _p	4542	5628	6866	6070	23106

Table 1 shows that the ribonucleic acid content of the acid phosphatase enzyme preparation treated soy protein material is 937 mg/kg or less [Total Nucleoside_{ap} – Monomerics_{ap}].

8. The experiment described in paragraph 7 above, conducted prior to August 25, 1999 in the United States, shows conception of a soy protein material containing at most 4000 mg/kg of ribonucleic acids, and of a soy protein material containing less than 2000 mg/kg of ribonucleic acids, and of a soy protein material containing less than 1500 mg/kg of ribonucleic acids prior to August 25, 1999 in the United States.
9. The experiment described in paragraph 7 above, conducted prior to August 25, 1999 in the United States, shows an actual reduction to practice of a soy protein material containing at most 4000 mg/kg of ribonucleic acids, and of a soy protein material containing less than 2000 mg/kg of ribonucleic acids, and of a soy protein material containing less than 1500 mg/kg of ribonucleic acids prior to August 25, 1999 in the United States.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful and false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 3/26/04

Theodore M. Wong
Theodore M. Wong

APPENDIX I

In re Marshall, 198 USPQ 344 (CCPA 1978)

In re Marshall □

(CCPA) □
198 USPQ 344

Decided June 30, 1978
No. 77-625
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability -- Anticipation -- In general (§ 51.201)

Patentability -- Anticipation -- Combining references (§ 51.205)

Rejections under 35 U.S.C. 102 are proper only when claimed subject matter is identically disclosed or described in prior art; in other words, all material elements recited in claim must be found in one unit of prior art to constitute anticipation; In re Samour, 197 USPQ 1, did not disturb this principle.

2. Patentability -- Anticipation -- In general (§ 51.201)

Accidental or unwitting duplication of invention cannot constitute anticipation.

3. Patentability -- Evidence of -- Suggestions of prior art (§ 51.469)

Patentability -- New use or function -- In general (§ 51.551)

Drug's known disadvantages that would naturally discourage search for new uses of that drug may be taken into account in determining obviousness.

Particular patents -- Weight Reduction

Marshall, Process for Weight Reduction, rejections of claims 1-9 reversed.

Case History and Disposition:

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Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of Edward M. Marshall, Serial No. 468,552, filed May 9, 1974. From decision rejecting claims 1-9, applicant appeals. Reversed; Markey, Chief Judge, with whom Baldwin, Judge, joins, dissenting in part, with opinion.

Attorneys:

Edward D. O'Brian, Anaheim, Calif., for appellant.

Joseph F. Nakamura (Jack E. Armore, of counsel) for Commissioner of Patents and Trademarks.

Judge:

Before Markey, Chief Judge, and Rich, Baldwin, Lane, and Miller, Associate Judges.

Opinion Text

Opinion By:

Lane, Judge.

This is an appeal from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) sustaining the examiner's rejection under 35 USC 102 of claims 1-4 and entering a new ground of rejection under 37 CFR 1.196(b) of claims 5-9 under 35 USC 103. We reverse both rejections.

Background

Invention

Normally, when food passes through the terminal region of the stomach, nerve endings there stimulate the release of two hormones, secretin and pancreozymin. These hormones then trigger the production and release of pancreatic enzymes necessary for digestion in the small intestine.

Applicant's weight control process involves anesthetizing these nerve endings with an orally administered anesthetic containing 50-2,000 mg of oxethazaine. This prevents the release of secretin and pancreozymin which in turn interferes with the production and release of the pancreatic enzymes. Thus, food passing through the small intestine is not digested and does not

contribute calories to the body.

The following claims are before us on appeal:

1. In a weight control process in which a quantity of food is consumed

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and passes through the gastrointestinal digestive tract of a living body the improvement which comprises:

said quantity of food including foodstuffs requiring digestion caused by pancreatic enzymes for absorption into the bloodstream from the small intestine,

periodically anesthetizing [sic] the nerve endings in the digestive tract which release hormones when contacted by food passing through the digestive tract so as to trigger the release of said pancreatic enzymes into the digestive tract by the pancreas prior to said quantity of food contacting said nerve endings only prior to the passage of food into said digestive tract, said anesthetization being carried out to an extent effective and at a time effective to inhibit said nerve endings from releasing sufficient hormones to cause the release of said pancreatic enzymes which will contact said food as it passes through the digestive tract,

said anesthetization serving to prevent the release of said hormones when said nerve endings are contacted by said quantity of food, this having the effect of preventing release of said enzymes by the pancreas to the digestive tract so that said food passes through the digestive tract without being digested so that it is [sic not] capable of being absorbed into the bloodstream as a consequence of the absence of said enzymes.

2. A weight control process as claimed in claim 1 wherein:

said nerve endings are anesthetized [sic] by orally taking a quantity effective to cause said inhibition of an anesthetic means coated with a coating means which is effective to delay the release of said anesthetic means until said anesthetic means reaches the vicinity of said nerve endings in the digestive tract.

3. A weight control process as claimed in claim 2 wherein:

said anesthetic means is oxethazaine.

4. A weight control process as claimed in claim 2 wherein:

said anesthetic means is orally taken with an adherence means for causing said anesthetic means to adhere to the interior of the digestive tract.

5. A weight control process as claimed in claim 4 wherein:

said adherence means is albumin and is admixed with said anesthetic means, said anesthetic means and said albumin both being coated with said coating means.

6. A weight control process as claimed in claim 2 wherein:

from about 50 to about 2,000 milligrams of said anesthetic means are taken at one

time, said time being prior to food being taken into the digestive tract.

7. A weight control process as claimed in claim 2 wherein:

from about 200 to about 800 milligrams of said anesthetic means are taken at one time, said time being prior to food being taken into the digestive tract.

8. A weight control process as claimed in claim 1 wherein:

said nerve endings are anesthetized [sic] by orally taking a quantity effective to cause said inhibition of an anesthetic means coated with a coating which will delay the release of said anesthetic means until said anesthetic means reaches the vicinity of said nerve endings in the digestive tract,

said anesthetic means is oxethazaine, and

from about 50 to about 2,000 milligrams of said anesthetic means are taken at one time, said time being prior to food being taken into the digestive tract.

9. A weight control process as claimed in claim 8 wherein:

said anesthetic means is orally taken with adherence means for causing said anesthetic [sic means] to adhere to the interior of the digestive tract, and

said adherence means is albumin and is admixed with said anesthetic [sic means], said anesthetic [sic means] and said albumin both being coated with said coating.

Prior Art

The reference relied upon are: the PHYSICIAN'S DESK REFERENCE 1522-23 (25th ed. 1971) (PDR); and J. Slayback, E. Swena, J. Thomas, L. Smith, The Pancreatic Secretory Response to Topical Anesthetic Block of the Small Bowel, 61 SURGERY 591 (1967) (Slayback).

The PDR describes drugs containing the anesthetic oxethazaine for the treatment of esophagitis, gastritis, peptic ulcer and irritable colon syndrome. The recommended adult oral dose of these drugs is one or two teaspoons (10-20 mg oxethazaine) four times daily, fifteen minutes before meals and at bedtime. The PDR expressly warns against exceeding the recommended dosage. Regarding the use of these drugs in the treatment of peptic ulcer, the PDR explains that topical appli

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cation of this local anesthetic inhibits the release of the acid-stimulating hormone, gastrin.

Slayback is an article reporting an investigation into the mechanism responsible for the release of the pancreatic secretory hormones, secretin and pancreozymin. Researchers found that application of the anesthetic oxethazaine HCl to isolated segments of the small intestine of surgically altered dogs caused a substantial reduction in the release of both secretin and pancreozymin. These results were consistent with the hypothesis that secretin and pancreozymin release is controlled by a local neural mechanism similar to the one which had been shown to control the release of the gastric secretory hormone, gastrin.

Proceedings Below

The examiner rejected claims 1-4 under 35 USC 102 as anticipated by the PDR and also rejected claims 1-9 under 35 USC 102/103 as anticipated or obvious over a patent to Pober.¹ The board affirmed the 102 rejection of claims 1-4 but reversed the 102/103 rejection of claims 1-9 and entered a new ground of rejection under 37 CFR 1.196(b) rejecting claims 5-9 under 35 USC 103 as obvious in view of the combined teachings of PDR and Slayback.²

Opinion

102 Rejection

[1] Rejections under 35 USC 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In *re Arkley*, 59 CCPA 804, 807, 455 F.2d 586, 587, 172 USPQ 524, 526 (1972). In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. *Soundscriber Corp. v. United States*, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct.Cl. 1966). This basic principle of patent law has not been disturbed by our recent decision, *In re Samour*, 571 F.2d 559, 197 USPQ 1 (CCPA 1978), in which we affirmed a §102(b) rejection of claims to a chemical compound based on a primary reference which disclosed the compound and additional references which established that a method of preparing the compound would have been obvious to one skilled in the art. In *Samour*, every material element of the claimed subject matter, the chemical compound, could be found in the primary reference, a disclosure of that compound.

[2] Applying this rule of law to the present case, we must reverse the board's rejection of claims 1-4 under 35 USC 102 since the primary reference, the PDR, does not disclose every material element of the claimed subject matter. These claims are directed to a weight control process. Applicant uses an effective amount of the anesthetic, oxethazaine, to inhibit release of the pancreatic secretory hormones, secretin and pancreaticozym, in order to control weight. The PDR, however, teaches using drugs containing the anesthetic oxethazaine to inhibit release of the acidstimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. Nothing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute an anticipation. In *re Felton*, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973).

103 Rejection

The board seems to have combined: (1) the teaching of the PDR that oral administration of oxethazaine inhibits release of gastrin, (2) the teaching of Slayback that secretin and pancreaticozym release is controlled by a local neural mechanism similar to the one which controls release of gastrin, and (3) the unrecognized fact that secretin and pancreaticozym control the production and release of pancreatic enzymes necessary for digestion in the small intestine, to conclude that applicant's method of controlling weight by anesthetizing the nerve endings that stimulate the release of secretin and pancreaticozym would have been obvious.

The problem with this rejection is that nowhere in any reference is there any suggestion to control weight by turning off the production and release of pancreatic enzymes. Although it has long been known that pancreatic enzymes are involved in digestion, from this record it appears that

applicant is the first to suggest controlling weight by decreasing the quantity of pancreatic enzymes in the small intestine. To say this would have been obvious is to resort to impermissible hindsight.

[3]Moreover, the PDR appears to teach away from using effective amounts of the anesthetic oxethazaine since it expressly cautions against exceeding the recommended dose of 10-20 mg. This would not be an effective amount for controlling weight by appellant's process. Although Slayback, which discusses tests conducted solely on dogs, recognizes that higher concentrations of oxethazaine will produce "complete absence of stimulation of hormonal release," this does not negate the PDR warning with respect to the oral administration to humans. Known disadvantages of a drug which would naturally discourage the search for new uses of that drug may be taken into account in determining obviousness. See *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 483-484 (1966).

Accordingly, for the reasons set forth herein, the decision of the board is *reversed*.³

Reversed

Footnotes

Footnote 1. U.S. patent No. 3,740,440, issued June 19, 1973, for "Method of Inhibiting Appetite for Food."

Footnote 2. The board does not explain why this new ground of rejection was not applied to claims 1-4 as well.

Footnote 3. The board rejected only claims 5-9 under 35 USC 103. In the interest of judicial economy, we note that our reversal of that rejection is not based on any limitations of claims 5-9 not found in broader claims 1-4 as well.

Dissenting Opinion Text

Dissent By:

Markey, Chief Judge, with whom Baldwin, Judge, joins, dissenting in part.

Though I wholeheartedly agree with the majority's treatment of the §102 issue, I respectfully dissent from the majority's conclusion of non-obviousness under §103.

The majority agrees that the board considered "the art recognized fact that secretin and pancreozymin control the production and release of pancreatic enzymes necessary for digestion in the small intestine." Nowhere in the record is there any dispute on that point. Moreover, the majority also recognizes that "it has long been known that pancreatic enzymes are involved in digestion."

Appellant and all others having ordinary skill in the art knew that pancreatic enzymes play a major role in the digestion of food. If food is not digested, it is excreted without being absorbed into the body. If food is not absorbed, the body cannot gain weight. It follows, therefore, that decreasing pancreatic enzyme quantity (or eliminating it altogether) must decrease weight. The particular compound chosen by appellant to shut off or decrease the flow of pancreatic enzymes was known in the art and used for that purpose.

- End of Case -

Mehl/Biophile International Corp. v. Milgraum (CA FC) 52 USPQ2d 1303

Mehl/Biophile International Corp. v. Milgraum

U.S. Court of Appeals Federal Circuit
52 USPQ2d 1303

Decided September 30, 1999
No. 99-1038

Headnotes

PATENTS

1. Patentability/Validity -- Anticipation -- Identity of elements (§ 115.0704)

Prior art manual for removing tattoos with lasers does not anticipate invention of patent

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for method of laser hair removal under principles of inherency, since asserted claim includes step of "aligning a laser light applicator substantially vertically over a hair follicle opening," since record discloses no necessary relationship between location of tattoo and location of hair follicles, since operator thus could use laser according to manual without necessarily aligning laser "substantially vertically" over follicle opening, and since possibility of such alignment does not legally suffice to show anticipation.

2. Patentability/Validity -- Anticipation -- Identity of elements (§ 115.0704)

Prior art article anticipates invention of patent for method of removing hair with laser under principles of inherency, since person of ordinary skill following teachings of article will align laser light applicator over hair follicle, such that article teaches claimed step of "aligning a laser light applicator substantially vertically over a hair follicle opening," since article includes many references to irradiation of hair follicles and resulting follicular damage, since fact that article concerns guinea pig skin rather than human skin is irrelevant, in that claimed method is not

limited to human skin, and since article's failure to mention hair depilation as goal is similarly irrelevant, in that authors' failure to appreciate result is of no import if, as here, result is necessary consequence of what was deliberately intended.

Particular patents -- General and mechanical -- Hair removal

5,059,192, Zaias, method of hair depilation, summary judgment of invalidity affirmed.

Case History and Disposition:

Page 1304

Appeal from the U.S. District Court for the District of New Jersey, Wolin, J.; 47 USPQ2d 1248 .

Action by Mehl/Biophile International Corp., Selvac Acquisitions Corp., and Nardo Zaias against Sandy Milgraum, Palomar Medical Technologies Inc., and Spectrum Medical Technologies Inc. for patent infringement. Plaintiffs appeal from grant of summary judgment of patent invalidity. Affirmed.

Attorneys:

Jeffrey A. Schwab, Michael Aschen, and Anthony J. DiFilippi, of Abelman, Frayne & Schwab, New York, N.Y.; George A. Arkwright, of Schlesinger, Arkwright & Garvey, Arlington, Va., for plaintiffs-appellants.

Wayne L. Stoner, William F. Lee, and James M. Hall, of Hale and Dorr, Boston, Mass.; Thomas A. Reed, of Palomar Medical Technologies Inc., Lexington, Mass., for defendants-appellees.

Judge:

Before Mayer, Michel, and Rader, circuit judges.

Opinion Text

Opinion By:

Rader, J.

In this patent infringement action, MEHL/Biophile International Corp., Selvac Acquisitions Corp., and Dr. Nardo Zaias (collectively, MEHL/Biophile) asserted that Dr. Sandy Milgraum,

Palomar Medical Technologies, Inc., and Spectrum Medical Technologies, Inc. (Milgraum) infringed U.S. Patent No. 5,059,192 (the '192 patent). On its motion for summary judgment, Milgraum contended that all of the '192 patent claims were anticipated by an instruction manual for the Spectrum RD-1200 laser and by a 1987 Journal of Investigative Dermatology article authored by Dr. Luigi Polla and others (the Polla article). The district court agreed that the manual anticipated the claims, granted summary judgment of invalidity, and dismissed the action. See *MEHL/Biophile Int'l Corp. v. Milgraum*, 8 F.Supp.2d 434, 47 USPQ2d 1248 (D.N.J. 1998). Although this court disagrees that the manual discloses all the elements of the claimed invention, because the Polla article does, this court affirms.

I.

The '192 patent, entitled "Method of Hair Depilation," claims a method for removing hair using a laser. Hairs grow out of hair follicles, tubular apertures in the skin. The collection of germ cells from which hairs grow, known as the papilla, lies at the base of the follicle. The '192 patent claims a method for destroying the papilla, thereby preventing hair regrowth. The written description discloses the use of a Q-switched ruby laser to effect the destruction.

At a meeting of the American Academy of Dermatology, Dr. Zaias visited Spectrum's booth where Spectrum displayed such a laser, known as the RD-1200. Spectrum sold the RD-1200 for use in removing tattoos. Dr. Zaias recognized that the same principles that govern laser absorption in skin pigmented by a tattoo would also focus laser absorption on the natural skin pigment found in the papilla. More specifically, the papilla contains granules (called melanosomes) of a dark pigment (called melanin). A Q-switched ruby laser aimed at the hair follicle will penetrate the skin and reach the

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papillary melanin. At a particular wavelength, the laser will heat up and destroy the papilla without damaging surrounding tissue.

Claim 1 of the patent, the only independent claim, reads:

1. A method of hair depilation, comprising the steps of: a) aligning a laser light applicator substantially vertically over a hair follicle opening, said applicator having an aperture of sufficient area to surround a hair follicle and overlie its papilla; b) applying through said aperture to the hair follicle a pulse of laser energy of a wavelength which is readily absorbed by the melanin of the papilla and having a radiant exposure dose of sufficient energy and duration to damage its papilla so that hair regrowth is prevented and scarring of the surrounding skin is avoided.

Dependent claims 2-6 further specify parameters of the laser light applicator, energy delivery, and the type of laser.

MEHL/Biophile sued Milgraum in the United States District Court for the District of New Jersey for infringement of all the claims of the '192 patent. Milgraum moved for summary judgment of invalidity based on 35 U.S.C. Section 102 (1994), arguing that two prior art references each teach all the limitations of the claims. As noted at the outset, Milgraum relied on the manual for the RD-1200 laser which describes the use of a laser to remove tattoos. The manual teaches the use of a Q-switched ruby laser to remove a tattoo: "[E]nergy is selectively absorbed only by pigmented chromophores and not surrounding tissue, greatly reducing the risk of scarring."

Milgraum also relied on the Polla article entitled "Melanosomes Are a Primary Target of Q-Switched Ruby Laser Irradiation in Guinea Pig Skin." The Polla article documents "the tissue

damage induced by Q-switched ruby laser pulses in black, brown, and albino (control) guinea pigs . . . in an effort to define the nature and extent of pigmented cell injury." The method involves epilating guinea pigs with soft wax, holding the aperture of the laser in contact with the skin, and pulsing the laser. Using an electron microscope, the researchers observed "disruption of melanosomes deep in the hair papillae."

The district court considered both references, but ultimately rested its decision on the RD-1200 manual. MEHL/Biophile appeals. MEHL/Biophile makes several arguments for disregarding the manual as an anticipating reference. For instance, MEHL/Biophile argues that the manual does not teach use of the laser to remove hair at all. Further MEHL/Biophile contends that the manual does not disclose a substantially vertical alignment, a claim element. As for the Polla article, MEHL/Biophile argues that the reference relates to guinea pig skin and does not mention hair depilation. In addition, MEHL/Biophile contends that the epilation of the guinea pig backs removed the papilla so the laser treatment could not have damaged the papilla.

II.

This court reviews a district court's grant of summary judgment by reapplying the standard applicable at the district court. *See Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed. Cir. 1994). Summary judgment is appropriate only when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). In its review, this court draws all reasonable inferences in favor of the non-movant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As this court's predecessor stated in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)) (internal citations omitted):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. *See In re Oelrich*, 666 F.2d at 581; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. *See In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency

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is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. *See id.*, 801 F.2d at 1326.

The RD-1200 Manual

The RD-1200 manual cannot anticipate because it does not teach all the limitations of the claimed invention. Claim 1 includes the step of "aligning a laser light applicator substantially vertically over a hair follicle opening." The parties agree that the manual does not discuss hair

follicles, let alone aligning the laser over a hair follicle opening. Thus, the manual does not explicitly teach alignment substantially vertically over a follicle opening. Without explicit teachings of this claim limitation, this court must nonetheless examine whether such alignment is inherent in the manual's disclosure.

[1] The manual teaches aiming the laser at skin pigmented with tattoo ink. The record discloses no necessary relationship between the location of a tattoo and the location of hair follicles. Therefore, an operator of the RD-1200 laser could use the laser according to the manual without necessarily aligning the laser "substantially vertically over a hair follicle opening." The possibility of such an alignment does not legally suffice to show anticipation. See *In re Oelrich*, 666 F.2d at 581. Occasional results are not inherent. Because this court holds that the manual does not inherently teach this limitation of the claimed invention, it does not address MEHL/Biophile's other arguments. To anticipate, a single reference must teach every limitation of the claimed invention. Without an inherent teaching about alignment, the manual does not anticipate the claimed invention.

The Polla Article

Although the district court did not reach the Polla article in its anticipation analysis, "[a]ppellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record." *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 822 n.1, 11 USPQ2d 1321, 1322 n.1 (Fed. Cir. 1989). Milgraum asserts that the Polla article constitutes such an alternative ground. This court agrees.

[2] As to the "aligning" step, the Polla article does not suffer from the same deficiency as the manual. It is not a question of probabilities as to whether a person of ordinary skill following the teachings of the article will align the laser light applicator over a hair follicle. The researchers focused their study on the epilated backs of guinea pigs. No one disputes that guinea pigs have hairy backs. Indeed, the article itself is replete with references to the irradiation of hair follicles and resulting follicular damage:

At 0.8 J/cm², epidermal lesions were more marked and involved hair follicles 0.3 mm below the skin surface [L]esions were also present 0.5 mm deep in follicles. [E]ven at the highest radiant exposure (1.2 J/cm²), brown [guinea pig] skin never showed full-thickness epidermal necrosis and at 0.8 J/cm², follicular damage was observed to a depth of 0.5 mm and at 1.2 J/cm² to a depth of 0.7 mm below the skin surface. . . . Follicular changes were similar in nature and extent to the epidermal alterations described above, and were associated with melanosome disruption. . . . Specifically, we have shown that . . . pigmented structures in the deep dermis such as hair follicles are affected

The article further contains a photograph showing "[f]ollicular changes induced by ruby laser." The changes include disruption of "melanosomes contained within follicular epithelium."

Moreover the article specifically mentioned disruption of the hair papillae:

At 0.8 and 1.2 J/cm², individual melanosomes were more intensely damaged and disruption of melanosomes deep in the hair papillae was observed.

Finally, the method of exposing the Q-switched ruby laser to the guinea pig skin also inherently teaches substantially vertical alignment over hair follicle openings:

The collimated laser beam struck a circular aperture, 2.5 mm in diameter, held in contact with the skin of the animals.

The record shows that holding the collimated laser in contact with the skin would align it perpendicular to the skin surface and therefore substantially vertically over follicle openings.

Viewed as a whole, this disclosure shows, in the words of *In re Oelrich*, 666 F.2d at 581, that

the "natural result flowing from the operation as taught would result in" alignment of the laser light over a hair follicle, as claimed. No reasonable jury could find otherwise. MEHL/Biophile's remaining arguments concerning the Polla article are unavailing. The Polla article concerns itself with guinea pig, rather than human, skin, but that difference

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is irrelevant to the anticipation analysis. Nothing in the claim limits the method's reach to human skin. Similarly, the Polla article's failure to mention hair depilation as a goal is similarly irrelevant. MEHL/Biophile does not dispute on appeal that the laser operating parameters disclosed in the article substantially coincide with those disclosed in the patent. Accordingly, to the extent the embodiment in the patent achieves hair depilation, so does the Polla method. Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results. See *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983). Finally, as mentioned earlier, the article itself belies MEHL/Biophile's argument that the wax epilation prescribed by the article resulted in removal of the papilla. The article specifically states that "disruption of melanosomes deep in the hair papillae was observed." MEHL/Biophile's expert testimony contradicting the plain language of the reference does not create a genuine issue of fact.

Thus, the Polla article anticipates claim 1 of the '192 patent. Because MEHL/Biophile has not separately argued the validity of the dependent claims, the judgment of invalidity as to those claims also stands.

COSTS

Each party shall bear its own costs.

AFFIRMED

- End of Case -

In re Oelrich and Divigard, 212 USPQ 323 (CCPA 1981)

In re Oelrich and Divigard

(CCPA)
212 USPQ 323

Decided Dec. 10, 1981

No. 81-564

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Court of Customs and Patent Appeals -- Issues determined -- Ex parte patent cases (§ 28.203)

Prior adjudication -- Applications for patent (§ 56.05)

Doctrine of res judicata argued in view of former case in which issue was obviousness is not applicable to instant anticipation rejection; furthermore, res judicata does not have its usual impact when considering ex parte patent appeals; public interest in

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granting valid patents outweighs public interest underlying collateral estoppel and res judicata, particularly where issue presented is not substantially identical to that previously decided.

2. Patentability -- New use or function -- In general (§ 51.551)

Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not distinguish claim drawn to those things from prior art.

3. Construction of specification and claims -- "Means" claims (§ 22.60)

Pleading and practice in Patent Office -- Rejections (§ 54.7)

Rejection of claim whose distinguishing feature is words after means for function phrase is

reversed where those words constitute limiting definition of means that is not expressly disclosed in reference nor inherent in it.

Particular patents -- Control Mechanism

Oelrich and Divigard, Sub-Critical Time Modulated Control Mechanism, rejection of claim 1 reversed.

Case History and Disposition:

Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of John A. Oelrich and Albert J. Divigard, Serial No. 452,050, filed Mar. 18, 1974. From decision rejecting claim 1, applicants appeal. Reversed.

See also 198 USPQ 210 .

Attorneys:

Roger A. Van Kirk, East Hartford, Conn., for appellants.

Joseph F. Nakamura and Thomas E. Lynch for Patent and Trademark Office.

Judge:

Before Markey, Chief Judge, and Rich, Baldwin, Miller, and Nies, Associate Judges.

Opinion Text

Opinion By:

Rich, Judge.

This appeal is from the decision of the United States Patent and Trademark Office (PTO) Board of Appeals (board) sustaining the examiner's rejection of claim 1 in application serial No. 452,050, filed March 18, 1974, entitled "Sub-Critical Time Modulated Control Mechanism," under 35 USC 102 as anticipated by appellant Oelrich's U.S. patent No. 3,430,536 for "Time Modulated Pneumatically Actuated Control Mechanism," issued March 4, 1969. We reverse.

Background

This application was the subject of *In re Oelrich*, 579 F.2d 86, 198 USPQ 210 (CCPA 1978), in which a rejection of claims 1-5 under 35 USC 103 was reversed. Appellant's method claims 2-5 now stand allowed.

The invention of claim 1 is directed to an apparatus specially adapted for moving low inertia

steering fins on guided missiles. The prior art apparatus and the theory upon which it operates are fully discussed in our above prior opinion and will, therefore, not be repeated here. Generally, the claimed device responds to an electric signal from a missile guidance system, the magnitude of which is proportional to the desired amount of course-correcting fin movement, and converts the signal into a pneumatic pressure of appropriate magnitude which acts on a piston to move the missile guiding fin. The device which is the subject of the Oelrich patent "was employed only with the then available steering fins which they characterize as 'high inertia' loads." ¹ The frequency at which this "high inertia" load system is operated is stated to be *above* the critical (resonant) frequency of the system. 579 F.2d at 87-89, 198 USPQ at 212-13. The allowed method claims and apparatus claim 1 direct use of a carrier frequency *below* the critical frequency of the system.

Claim 1 reads (emphasis ours):

1. A time modulated fluid actuated control apparatus comprising:

housing means, said housing means defining a cylinder;

actuator piston means disposed in said housing means cylinder, said piston means including an output member adapted to be connected to a movable load, said load and control apparatus

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defining a system having a range of resonant frequencies;

solenoid operated valve means mounted on said housing means, said valve means being selectively operable to deliver pressurized fluid to and to vent fluid from said housing means cylinder at one side of said piston means;

means for generating variable input command signals commensurate with the desired position of the load, said command signals being characterized by a dynamic frequency range *below said range of said resonant frequencies*;

means for generating a signal at a *carrier frequency*, said carrier frequency being *greater than the maximum dynamic command signal frequency and less than the minimum system resonant frequency*;

means for modulating said carrier frequency signal by said command signals; and

means responsive to said modulated carrier frequency signal for controlling energization of said solenoid operated valve means.

In sustaining the examiner's rejection under §102, the board expressed agreement with his reasoning, which is here summarized. Stating that "the issue is identical to that decided in *In re Ludtke*, 58 CCPA 1159, 441 F.2d 660, 169 USPQ 563 (1971)," the examiner noted that, for purposes of determining inherency, "the question is, does Oelrich [the reference patent] disclose a signal generator that necessarily must supply the carrier frequencies that appellants use?" The examiner turned to Exhibit A of coapplicant Divigard's affidavit, which states as an assumption in a "Linearized Simulation" of a "high inertia" load system that the critical resonance frequency must be kept below 80 Hz to avoid interaction with the carrier frequency which is between 100 and 150 Hz. Thus, the examiner concluded, "Exhibit A establishes Oelrich's carrier frequency

range, which may now be compared with the carrier frequency range of applicants' low-inertia system." It was then asserted that the Oelrich and Kolk affidavits establish that good low inertia system design practice dictates a carrier frequency range of 95-190 Hz. Since the carrier frequency range for the high inertia system lies within the range for the low inertia system, and since the critical frequency of the low inertia system is near the solenoid limit of 175 Hz, the examiner posited that the Oelrich carrier frequencies would be sub-critical in the low inertia system, saying, "Thus Oelrich's signal generator does in fact inherently produce frequencies which would be sub-critical when used with a low-inertia system, and therefore, inherently supplies a carrier frequency range which is usable in applicants' system since this conclusion was deduced from specific data presented in the patent and in the affidavits supplied by appellants." The appellants also asserted our prior decision was *res judicata*.

Opinion

[1] Although appellants' arguments on appeal are directed primarily to a discussion of *res judicata*² and whether a "product which is unwittingly produced is anticipation," resolution of this case is properly had by comparison of the reference patent to the limitations of claim 1. As will appear, the determinative issue is a question of inherency.

The distinguishing feature of claim 1 is defined in the paragraph which states that the apparatus contains a

means for generating a * * * carrier frequency * * * greater than the maximum dynamic command signal frequency and *less than* the minimum system resonant frequency.³

Given that the carrier frequency which can be used in a low inertia system *may* fall within the range of carrier frequencies usable in a high inertia system (appellants admit as much), the PTO urges that the apparatus of the Oelrich patent inherently performs the function of the apparatus of claim 1, and that finding a new use for an old device does not entitle one to an apparatus claim for that device, citing *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). Appellants in that case argued, however, that a structure suggested by the

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prior art was patentable to them because it also possessed an *inherent but unknown* function which they claimed to have discovered. This court stated that a "patent on such a structure would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art." *Id.* at 1023, 201 USPQ at 661.

Appellants here countered the PTO inherency contention at oral argument (no reply brief was filed) by urging that there is no "inherency" because there is no "inevitability," that is, the previously quoted "means plus function" limitation of claim 1 is not inherently (always) present in the device of the Oelrich patent.

[2] It is true that mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not distinguish a claim drawn to those things from the prior art. *In re Swinehart*, 58 CCPA 1027, 1031, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (1971). In this case, however, claim 1 does not merely recite a newly discovered function of an old device. *In re Chandler*, 45 CCPA 911, 254 F.2d 396, 117 USPQ 361 (1958), a case not cited

by either party to this appeal, is most pertinent to the instant controversy.

The claim in *Chandler*, id. at 912-13, 254 F.2d at 397, 117 USPQ at 361-62, drawn to an automatic control for a jet engine, included a "means responsive to said movement for regulating the propulsive power of said engine, in accordance with said movement, *so that* said aircraft is propelled at a definite, selected speed, corresponding to the position of said engine relative to said aircraft, throughout the speed range of said aircraft." (Emphasis added.) In refuting the examiner's argument that the words beginning with "so that" were merely functional, and thus did not distinguish the device from that claimed in a patent to Goddard, this court stated:

* * * the expression beginning with "so that" is not merely functional, but constitutes a part of the definition of the "means responsive to said movement." Thus that means is defined as being responsive to the movement of the engine in such a way that the aircraft will be propelled at a definite speed in the manner specified. Such a definition conforms to the provision of 35 U.S.C. 112 that an element in a claim for a combination "may be expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof." ⁴

[3] Likewise, the words after "means for generating a * * * carrier frequency" in the claim on appeal constitute a limiting definition of the means. The PTO does not contend that this limitation, a carrier frequency which is "less than the minimum system resonant frequency," is expressly disclosed in the Oelrich patent. Neither, however, is this limitation inherent therein. In *Hansgirk v. Kemmer*, 26 CCPA 937, 940, 102 F.2d 212, 214, 40 USPQ 665, 667 (1939), the court said:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

The relationship between the carrier frequency and the system critical frequency -- the former below the latter (and expressly made a claim limitation by use of "means plus function" language) -- cannot be said to be "the natural result flowing from the operation as taught." The Oelrich patent instructs that the device is "adapted to receive a carrier frequency substantially in excess of the particular system critical or resonant frequency* * *." Given this express teaching, a "means for generating a* * *carrier frequency* * *less than the minimum system resonant frequency" is not inevitably present.

The decision of the board is *reversed*.

Reversed.

Footnotes

Footnote 1. While the solicitor equates "low-inertia" with a "relatively light load" and "high-inertia" with a "relatively heavy load," appellants are not as unequivocal. They refer to "small inertia" and "low inertia" loads, but, for example, the Divigard affidavit refers to "Fin Inertia" in terms of "in-lb sec ²/rad," a unit of measure applicable only in referencing *moment of*

inerita, not *inertia*. The difference is significant because inertia, measured in terms of *mass*, is closely related to *weight*, while moment of inertia is affected by the *distribution* of the mass. Because of this ambiguity, we cannot and do not use the terms "weight" and "inertia" interchangeably.

Footnote 2. The doctrine of res judicata, argued in view of our decision in *In re Oelrich*, 579 F.2d 86, 198 USPQ 210 (CCPA 1978), is not applicable to the instant rejection. The issue in the former case was obviousness; here it is anticipation. A new rejection is before us. Furthermore, res judicata does not have its usual impact when considering ex parte patent appeals; the public interest in granting valid patents outweighs the public interest underlying collateral estoppel and res judicata, particularly where the issue presented is not substantially identical to that previously decided. *In re Russell*, 58 CCPA 1081, 1083, 439 F.2d 1228, 1230, 169 USPQ 426, 428 (1971); *In re Craig*, 56 CCPA 1438, 1441-42, 411 F.2d 1333, 1335-36, 162 USPQ 157, 159 (1969).

Footnote 3. Emphasis is ours. Portions of the claim unnecessary to this discussion have been omitted for clarity.

Footnote 4. For a similar case, see *In re Wilson*, 53 CCPA 1141, 1148-49, 359 F.2d 456, 461, 149 USPQ 523, 527 (1966). The provision of §112 referred to is, of course, the sixth paragraph, formerly, at the times of Chandler and Wilson, the third paragraph. The change occurred January 24, 1978.

- End of Case -

Trintec Industries Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597 (CA FC 2002)

63 USPQ2D 1597

Trintec Industries Inc. v. Top-U.S.A. Corp.

U.S. Court of Appeals Federal Circuit

No. 01-1568

Decided July 2, 2002

Headnotes

PATENTS

[1] Patentability/Validity — Anticipation — Identity of elements (§115.0704)

Patent construction — Claims — Defining terms (§125.1305)

Claims of patent for method of making multicolor faces for watches and other instruments using computer and color photocopier are not inherently anticipated by catalogue that advertises method of making customized watch faces using color printer, since, as matter of correct claim construction, “color photocopier” requires ability to both print and photocopy subject matter with color, since difference between photocopier and printer may be minimal and obvious to those of skill in art, but obviousness is not inherent anticipation, and since catalogue therefore does not disclose, either expressly or inherently, use of color photocopier.

[2] Patentability/Validity — Anticipation — Identity of elements (§115.0704)

Patent construction — Claims — Broad or narrow (§125.1303)

Claim of patent for method of making multicolor faces for watches and other instruments, which includes step of “creating” instrument face “in the computer” in electronic format, is not inherently anticipated by catalogue that advertises various methods of making customized watch

faces using color printer, since claim step in question cannot be broadly interpreted to require "creating or providing" instrument face in computer, since "creating" requires substantive addition or modification of artwork in computer, and since printing methods advertised in catalogue,

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in which computer serves merely as conduit for printing, disclose nothing about creating artwork in computer.

Particular Patents

Particular patents — General and mechanical — Instrument faces

5,818,717, Nunes, automated small volume production of instrument faces, summary judgment of invalidity vacated.

Case History and Disposition

Appeal from the U.S. District Court for the Southern District of Ohio, Kinneary, S.J.

Action by Trintec Industries Inc. against Top-U.S.A. Corp. for patent infringement. Plaintiff appeals from summary judgment of patent invalidity. Vacated and remanded.

Attorneys:

Robert A. Vanderhye, of Nixon & Vanderhye, Arlington, Va., for plaintiff-appellant.

David P. Shouvlin, David W. Costello, and Richard M. Mescher, of Porter, Wright, Morris & Arthur, Columbus, Ohio, for defendant-appellee.

Judge:

Before Mayer, chief judge, Rader and Gajarsa, circuit judges.

Opinion Text

Opinion By:

Rader, J.

On summary judgment, the United States District Court for the Southern District of Ohio found Trintec Industries, Inc.'s United States Patent No. 5,818,717 ('717 patent) invalid as inherently anticipated. *Trintec, Indus. v. Top-U.S.A. Corp.*, No. C-2-99-1179 (S.D. Ohio Jun. 19, 2001). Because the '717 patent is not inherently anticipated, this court vacates and remands.

I.

Trintec is the assignee of the '717 patent. The inventor, Brendon G. Nunes, filed the '717 patent application on June 2, 1993. The '717 patent claims a cost-effective method of producing, in low volume, multicolor faces for watches, clocks, thermometers and other instruments. The

method includes making a graphic instrument face in a computer, transmitting electronic signals from the computer to a color printer or photocopier, printing the face on sheet material, cutting it, and assembling it into an instrument.

Top-U.S.A. Corporation produces watches and clocks with customized faces, and has done so for over eighteen years. Initially, Top created and printed its customized graphics using pad printing, engraving, silk screening, or photography. Those methods were expensive and required extensive set-up time. Thus, these older methods were ill-suited to small-volume custom design and printing. Desktop publishing's advent in the late 1980s mitigated the design side of this problem, but high-resolution color printing remained prohibitively expensive. With color laser printer advances, however, Top was using that technology to make custom watches and clocks by 1995.

Sweda Company LLC also is in the customized watch business. In a 1991-92 catalogue (Sweda catalogue), Sweda advertised the availability at an inexpensive price of small-volume multi-color watches produced by "a new computer laser printer." The Sweda catalogue was not before the examiner of the '717 patent during its prosecution.

On November 2, 1999, Trintec asserted the '717 patent against Top in the district court. Trintec alleged that Top infringed independent claims 3 and 8, and associated dependent claims 4-5, 12, and 13. Trintec filed a motion for summary judgment of infringement, intentional infringement, and validity. Top filed a cross-motion for summary judgment that the asserted claims either were anticipated or obvious in view of the Sweda catalogue. The district court found that the Sweda catalogue inherently anticipated the asserted claims and granted summary judgment of invalidity. Having determined that prior art anticipated the '717 patent, the district court did not reach obviousness and dismissed the case with prejudice. Trintec appeals the district court's summary judgment of invalidity. This court has jurisdiction under 28 U.S.C. § 1295(a)(1) (2000).

II.

This court reviews a district court's grant of summary judgment without deference. *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1353, 47 USPQ2d 1705, 1713 (Fed. Cir. 1998). This court also reviews without deference questions of claim construction. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (*en banc*). Novelty, or anticipation, is a question of fact. *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986). Therefore, a district court properly may grant summary judgment

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on this identity question only when the record discloses no genuine material factual issues.

Because novelty's identity requirement applies to claims, not specifications, *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057, 1064 (Fed. Cir. 1988), the anticipation inquiry first demands a proper claim construction. Claim language defines claim scope. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121, 227 USPQ 577, 586 (Fed. Cir. 1985) (*en banc*). As a general rule, claim language carries the ordinary meaning of the words in their normal usage in the field of invention. *Toro Co. v. White Consol. Indus.*, 199 F.3d 1295,

1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). Nevertheless, the inventor may act as his own lexicographer and use the specification to supply implicitly or explicitly new meanings for terms. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80, 34 USPQ2d 1321, 1330 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 [38 USPQ2d 1461] (1996). Thus, a construing court may consult as well the written description, and, if in evidence, the prosecution history. *Id.*

A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Inherent anticipation requires that the missing descriptive material is “necessarily present,” not merely probably or possibly present, in the prior art. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991)).

In this case, the district court determined that the Sweda catalogue anticipated, or disclosed and enabled each and every element of, the claimed invention. The Sweda catalogue advertises three different methods of making customized watches: a “full color watch rendering” method, a “mock-up sample” method, and a “speculative sample” method. The catalogue states that the first two methods use a computer laser printer, and the “speculative samples” method uses silk-screening, hot stamping, color process/offset printing, etchograph stamping, or engraving. The catalogue then shows images of color watch faces made with each of the advertised methods. All three methods require the customer to submit “camera ready, color separated artwork,” i.e., separate pieces of black and white artwork representing each color in the design.

Top concedes that the Sweda catalogue does not teach expressly all limitations of the asserted claims. Hence, the only issue for this court to determine is whether the claim limitations not taught expressly by the Sweda catalogue are nevertheless disclosed inherently. This inherent anticipation question implicates claims 3 and 8. Claim 3 recites, in relevant part:

3. A method of constructing a functional multicolor element having indicia thereon, utilizing a computer and a *color photocopier*, comprising the steps of:

(a) electronically creating or providing in the computer an electronic simulation of the desired functional multicolor element, with indicia thereon;

(b) under the control of the computer, transmitting electronic signals from the computer to the *photocopier* so that the *photocopier* transforms the electronic simulation of the desired functional multicolor element onto a piece of sheet material

Col. 7, ll. 16-26 (emphases added).

The district court construed the term “color photocopier” to mean a “color printer.” The district court noted that the Sweda catalogue expressly advertises: “A color picture of your customers custom logo produced by our new advanced computer laser printer.” Based on this, the district court determined that the Sweda catalogue inherently disclosed a color printer because “those in the graphic arts industry would have recognized that a color printing device is necessarily present in the catalogue's description of ‘a full color rendering’ produced from a ‘computer laser printer.’” Nevertheless, a color printer is not a color photocopier.

[1] The '717 patent specification teaches that a “major component” of the invention “is a printer, preferably a color photocopier.” Col. 3, ll. 62-64. At the same time, the patent also recognizes

that a color photocopier does more than print in color—it copies. Specifically, the specification teaches “photocop[ying] with a color photocopier, such as of the types earlier described.” Col. 6, ll. 20-21. The undisputed trial testimony of Dr. Steven J. Bares underscores this point: “Digital color copiers comprise

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a digital color scanner and a digital color laser printer which are directly connected together so that graphics transformed into digital information through the scanner are transmitted to the digital color laser printer for printing.” As a matter of correct claim construction, therefore, a “color photocopier” requires the ability both to print and photocopy subject matter with color.

The difference between a printer and a photocopier may be minimal and obvious to those of skill in this art. Nevertheless, obviousness is not inherent anticipation. *Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021, 1025 (Fed. Cir. 1984) (“though anticipation is the epitome of obviousness, [they] are separate and distinct concepts”). Given the strict identity required of the test for novelty, on this record no reasonable jury could conclude that the Sweda catalogue discloses either expressly or inherently a color photocopier. Because claim 3 is not inherently anticipated, dependent claims 4 and 5 also are not anticipated.

Claim 8 recites, in relevant part:

8. A method of producing an instrument face having functional indicia thereon, utilizing a computer and printer, comprising the steps of:

(a) *creating* the instrument face with functional indicia thereon *in the computer* in electronic format

Col. 8, ll. 1-5 (emphases added). While claim 3 has the broader language “creating or providing,” claim 8 recites only “creating.” Nonetheless, the district court interpreted both claims to require “*creating or providing* in a computer a multicolor logo and hour markings to comprise the face of an instrument.” (Emphasis added.) The district court found that the Sweda catalogue inherently anticipated “creating or providing” as required by its claim construction. Because claim 8 requires “creating” rather than “creating or providing,” the district court erred in its construction of that claim and in its corresponding determination of inherent anticipation.

[2] The '717 patent does not define expressly “creating” or “providing.” The two terms, however, have distinct meanings. Each term appears in claim language. Each therefore imparts a different scope to the claim in which it appears. *See, e.g., Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562, 19 USPQ2d 1500, 1503 (Fed. Cir. 1991) (“The fact that mitered linear border pieces meet to form a right angle corner does not make them right angle corner pieces, when the claim separately recites both linear border pieces and right angle corner border pieces.”).

In its teachings, the specification treats the two terms differently. For example, with respect to preparing an instrument face for printing, the specification describes a two step process: “The artwork ... is *created in electronic format in the computer*. Information may initially be inputted into the computer for this purpose from a conventional scanner or a CD ROM.” Col. 4, ll. 7-11 (emphasis added). In sum, the patent recognizes that information may be provided (input) into the computer after creation elsewhere or, alternatively, may be created in the computer from scratch. Regarding the creating step, the specification further teaches that “commercially available software programs” may be used to “produce almost any design desired on an

instrument face.” Col. 4, ll. 11-14, 18. In view of these teachings, this court construes “creating” to require more than simply using the computer as a conduit to convey information to the printer from a scanner or a CD ROM. Creating requires, rather, a substantive addition or modification of the artwork in the computer, such as when graphics software adds a design to an instrument face.

The Sweda catalogue discloses, as discussed above, various printing methods. These printing methods disclose nothing about creating artwork in a computer. For this reason, the Sweda catalogue does not inherently anticipate claim 8. Specifically, the Sweda catalogue may well have created instrument faces with conventional manual methods. Then after manual creation or assembly, the Sweda catalogue may have provided those faces to a computer only for printing. Indeed, the Sweda catalogue required expressly that its customers provide color separations of their artwork. The record suggests that those of skill in this art use color separations to create manually a composite color rendering of the desired image. Then a black and white laser printer makes separate transparent color sheets based on the color separations. Finally, the artisans overlay the separate color sheets manually to form a composite color rendering of the desired image. This process requires no substantive addition or modification of the artwork in the computer — as mandated by a correct

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reading of the term “create.” In other words, the process suggested by the Sweda catalogue combines the color sheets outside of the computer, with the computer serving merely as a conduit for printing. It is irrelevant that a skilled artisan might possibly use the computer to create the final desired image from the color separations. Inherency does not embrace probabilities or possibilities. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999). In sum, no reasonable jury could find that the Sweda catalogue anticipates either expressly or inherently this claim.

Cases involving novelty, with its strict identity requirement, are quite rare. Obviousness seems the actual issue here. This court, however, cannot reach that question without a fully developed record. Obviousness involves, for instance, questions of suggestion to combine, *see, e.g., In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998), and objective indicators of patentability, *see, e.g., Graham v. John Deere Co.*, 383 U.S. 1, 17-18 [148 USPQ 459] (1966). On appeal, this court cannot venture into these factual and complex areas without a developed record. Accordingly, this record requires remand to permit the trial court to apply the obviousness standards in light of the Sweda catalogue and other prior art as viewed with the knowledge of one of skill in the art at the time of invention.

CONCLUSION

Because the district court erred in granting summary judgment that claims 3-5, 8, 12, and 13 are inherently anticipated, this court vacates and remands for a determination on the issue of obviousness and other proceedings consistent with this opinion.

COSTS

Each party shall bear its own costs.

VACATED AND REMANDED

**- End of Case -
A0A5W0G2M2**

In re Robertson (CA FC) 49 USPQ2d 1949

In re Robertson ☐

U.S. Court of Appeals Federal Circuit ☐
49 USPQ2d 1949 ☐

Decided February 25, 1999 ☐
No. 98-1270

Headnotes

PATENTS

1. Patentability/Validity -- Anticipation -- In general (§ 115.0701)

Element of claim is not "inherent" in disclosure of prior art reference unless extrinsic evidence clearly shows that missing descriptive matter is necessarily present in thing described in reference, and that it would be so recognized by persons of ordinary skill; inherency may not be established by mere probabilities or possibilities, and mere fact that certain thing may result from given set of circumstances is not sufficient.

2. Patentability/Validity -- Anticipation -- Identity of elements (§ 115.0704)

Board of Patent Appeals and Interferences improperly rejected application claim for fastening and disposal system for diapers on ground that prior reference inherently contained all elements of claim, since board failed to recognize that third mechanical fastening means of application claim, used to secure diaper for disposal, was separate from and independent of two other means used to attach diaper to wearer, and since board's theory that two fastening devices in reference were capable of being intermingled to perform same function as third and first fastening elements in application claim rests upon mere probability or possibility that is insufficient to establish inherency.

Case History and Disposition:

Page 1949

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Anthony J. Robertson and Charles L. Scripps, serial no. 08/171,484 (fastening and disposal system for diapers). Applicants appeal from rejection of application claim 76 on grounds of anticipation and obviousness. Reversed; Rader, J., concurring in separate opinion.

Attorneys:

Kenneth R. Adamo and Calvin P. Griffith, of Jones, Day, Reavis & Pogue, Cleveland, Ohio; Gregory A. Castanias, of Jones, Day, Reavis & Pogue, Washington, D.C.; Steven W. Miller, of Procter & Gamble Co., Cincinnati, Ohio, for appellants.

Linda Moncys Isacson, associate solicitor, Albin F. Drost, acting solicitor, and John M. Whealan, associate solicitor, U.S. Patent and Trademark Office, Arlington, Va., for appellee.

Judge:

Before Newman, circuit judge, Friedman, senior circuit judge, and Rader, circuit judge.

Opinion Text

Opinion By:

Friedman, S.J.

This appeal challenges the decision of the Board of Patent Appeals and Interferences

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(Board) that claim 76 in the appellants' patent application was anticipated by and obvious over United States Patent No. 4,895,569 (the Wilson patent). We reverse.

Both claim 76 and Wilson involve fastening and disposal systems for diapers. In both, the body of the diaper features a small front and a larger rear section. The outer edges of those sections

are attached at the wearer's waist in the hip area. Once the diaper is soiled and then removed, the smaller front section is rolled up into the larger rear section and secured in this rolled-up configuration by fasteners.

The appellants' application is for "an improved mechanical fastening system for . . . disposable absorbent articles [*i.e.* , diapers] that provides convenient disposal of the absorbent article."

[J.A. 12] Claim 76 covers:

[A] mechanical fastening system for forming side closures . . . comprising a closure member . . . comprising a first mechanical fastening means for forming a closure, said first mechanical fastening means comprising a first fastening element; a landing member . . . comprising a second mechanical fastening means for forming a closure with said first mechanical fastening means, said second mechanical fastening means comprising a second fastening element mechanically engageable with said first element; and disposal means for allowing the absorbent article to be secured in a disposal configuration after use, said disposal means comprising a third mechanical fastening means for securing the absorbent article in the disposal configuration, said third mechanical fastening means comprising a third fastening element mechanically engageable with said first fastening element .

Claim 76 thus provides for two mechanical fastening means to attach the diaper to the wearer and a third such means for securing the diaper for disposal.

The Wilson patent discloses two snap elements on fastening strips attached to the outer edges of the front and rear hip sections of the garment. The fastening strips may also include "secondary load-bearing closure means" -- additional fasteners to secure the garment; they may be identical to the snaps.

Wilson also states:

[D]isposal of the soiled garment upon removal from the body is easily accomplished by folding the front panel . . . inwardly and then fastening the rear pair of mating fastener members . . . to one another, thus neatly bundling the garment into a closed compact package for disposal.

[JA 085 at col. 6, 11, 20-25]

In other words, Wilson does not provide a separate fastening means to be used in disposing of the diaper. Instead, it suggests that disposal of the used diaper may be "easily accomplished" by rolling it up and employing the same fasteners used to attach the diaper to the wearer to form "a closed compact package for disposal."

In holding that the invention claim 76 covers was anticipated by Wilson, the Board did not hold that Wilson set forth a third fastening means. Instead, it found that Wilson anticipated claim 76 "under principles of inherency." [J.A. 5] Applying the language of claim 76 to the operation of Wilson, it concluded that "an artisan would readily understand the disposable absorbent garment of Wilson . . . as being inherently capable of [making the secondary load-bearing closure means] (third fastening element) mechanically engageable with [the other snap fasteners on the fastening strip] (first fastening element)" [J.A. 5] -- *i.e.* , using the secondary closure not with its mate, but with one of the primary snap fasteners. The Board summarily affirmed the examiner's alternative ruling that claim 76 would have been obvious in light of Wilson because "claim 76 lacks novelty." [J.A. 7]

II

Anticipation under 35 U.S.C. Section 102(e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.* , 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir.

1987).

A. The Wilson patent does not expressly include a third fastening means for disposal of the diaper, as claim 76 requires. That means is separate from and in addition to the other mechanical fastening means and performs a different function than they do. Indeed, Wilson merely suggests that the diaper may be closed for disposal by using the same fastening means that are used for initially attaching the diaper to the body.

[1] B. If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that

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it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269, 20 U.S.P.Q.2d at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

In finding anticipation by inherency, the Board ignored the foregoing critical principles. The Board made no attempt to show that the fastening mechanisms of Wilson that were used to attach the diaper to the wearer also "necessarily" disclosed the third separate fastening mechanism of claim 76 used to close the diaper for disposal, or that an artisan of ordinary skill would so recognize. It cited no extrinsic evidence so indicating.

[2] Instead, the Board ruled that one of the fastening means for attaching the diaper to the wearer also could operate as a third fastening means to close the diaper for disposal and that Wilson therefore inherently contained all the elements of claim 76. [J.A. 5] In doing so, the Board failed to recognize that the third mechanical fastening means in claim 76, used to secure the diaper for disposal, was separate from and independent of the two other mechanical means used to attach the diaper to the person. The Board's theory that these two fastening devices in Wilson were capable of being intermingled to perform the same function as the third and first fastening elements in claim 76 is insufficient to show that the latter device was inherent in Wilson. Indeed, the Board's analysis rests upon the very kind of probability or possibility -- the odd use of fasteners with other than their mates -- that this court has pointed out is insufficient to establish inherency.

III

The Board's entire discussion of obviousness was as follows: *The rejection of claim 76 under 35 USC Section 103*

We sustain the rejection of claim 76 under 35 USC Section 103. Above, we found that claim 76 lacks novelty. Lack of novelty is the ultimate of obviousness. See *In re Fracalossi*, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982). Thus, claim 76 is appropriately rejected under 35 USC Section 103 as being unpatentable.

The "lack of novelty" upon which the Board based its conclusion of obviousness, however, was its finding of anticipation. Our rejection of that finding eliminates the sole basis of the Board's obviousness determination, which therefore cannot stand. See *In re Adams*, 364 F.2d 473, 480, 150 U.S.P.Q. 646, 651 (C.C.P.A. 1966).

In his brief the Commissioner argues:

Moreover, even if this court interprets claim 76 to require two separate fasteners to perform the closure and disposal functions, it would have been well within the knowledge of one of ordinary skill in the art to take Wilson's one fastener and make it into two separate fasteners. See [*In re*] *Graves* , 69 F.3d [1147,] 1152, 36 USPQ2d [1697,] 1701 [(Fed. Cir. 1995)] (When evaluating a reference, it is appropriate to consider the knowledge of a skilled artisan in combination with the teaching of the reference.). Accordingly, claim 76 would have been obvious to one of ordinary skill in the art, and the rejection should be affirmed by this Court.

That, of course, was not the ground on which the Board based its obviousness ruling. We decline to consider counsel's newly-minted theory as an alternative ground for upholding the agency's decision. See *In re Soni* , 54 F.3d 746, 751, 34 U.S.P.Q.2d 1684, 1688 (Fed. Cir. 1995) (citing *In re DeBlauwe* , 736 F.2d 699, 705 n.7, 222 U.S.P.Q. 191, 196 n.7 (Fed. Cir. 1984)). The Board's obviousness ruling cannot be sustained on the ground given by the Board.

CONCLUSION

The decision of the Board of Patent Appeals and Interferences affirming the examiner's rejection of claim 76 as anticipated by and obvious over the Wilson patent is

REVERSED .

Rader, J., concurring.

Robertson asserts that the prior art Wilson patent does not teach three elements of claim 76: a "third mechanical fastening means," a disposal means on the "outside surface" of the body portion, and end regions that are "in an overlapping configuration when worn." In reversing the Board, this court relies solely on the purported failure of Wilson to teach the third fastening means. Because I believe Wilson teaches such a means, but does not teach the other two limitations at issue, I concur.

In its analysis, this court assumes without discussion that the claimed "third mechanical fastening means" covers a *separate* third mechanical

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fastening means. This issue is key, for if the claim does not require a separate third fastening means, but instead allows the first fastening means to also serve as the third, then the prior art Wilson patent clearly teaches that element of the claim. For two reasons, this claim does not, to my eyes, require a separate third fastening means. First, the claim does not specifically recite a *separate* third fastening means. Second, because the claim is in means-plus-function form, this court consults the specification to identify structure. The specification explicitly teaches that the first and third fastening elements can be the same so long as they are complementary, as they are in Wilson. Accordingly, I agree with the Board that Wilson teaches the claimed "third fastening element."

Wilson does not, however, teach either of the other two claim limitations at issue. As to the disposal means on the "outside surface" of the body portion, Wilson's figs. 12 and 13a-d show the disposal means on the inside of the body portion. As to the end regions that are "in an overlapping configuration when worn," Wilson explicitly teaches that the end regions should abut, not overlap, when worn. To overcome these teachings, the Board relied on the following statement in Wilson: "Further, the fastener members need not be previously mounted on a separate strip as shown then bonded . . . to the stretchable outer cover Multi-component snaps are available which may be applied directly to a stretchable outer cover material"

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Col. 7, l. 65 to col. 8, l. 3. The Board opined that applying snaps directly to the outer cover would result in both a disposal means on the "outside surface" and end regions "in an overlapping configuration when worn." Simply put, the Board has put more weight on this teaching than it can bear. It is far from clear what effect applying the snaps directly to the outer cover will have on the Wilson diaper configuration, let alone that it will result in a configuration satisfying the claim elements at issue. Accordingly, because I believe that the Board clearly erred in this interpretation of Wilson, I would reverse on this ground.

- End of Case -

Rosco Inc. v. Mirror Lite Co., 64 USPQ2d 1676 (CA FC 2002)

64 USPQ2D 1676
Rosco Inc. v. Mirror Lite Co.

U.S. Court of Appeals Federal Circuit

Nos. 01-1271, -1302
Decided September 24, 2002

Headnotes

PATENTS

[1] Patentability/Validity — Design patents (§115.17)

Design patent for oval-shaped “cross-view” school bus mirror is not invalid for functionality, since mere fact that claimed mirror exhibited superior field of view over single predecessor mirror does not establish that design was “dictated by” functional considerations, since record shows that other mirrors having non-oval shapes offer same field of view, since nothing in record connects oval shape of patented design with superior aerodynamics, and since record shows that other non-oval shaped mirrors have same aerodynamic effect as claimed design.

[2] Patentability/Validity — Anticipation — Identity of elements (§115.0704)

“Varying rate of curvature” limitation in claims for “cross-view” school bus mirror is not inherently disclosed in prior art design patent, since reference inherently anticipates only if missing element is necessarily present in thing described in reference, and would be so recognized by persons of ordinary skill in art, since design patent does not specify vacuum thermoforming process that may produce varying rate of curvature, and since there is nothing in record to support finding that person skilled in art would read design patent as disclosing mirror having varying rate of curvature along major axis of its lens.

[3] Patentability/Validity — Date of invention — In general (§115.0401)

Patentability/Validity — Anticipation — Identity of elements (§115.0704)

Record does not support finding that patent for “cross-view” school bus mirror, which claims mirror having “varying rate of curvature” along major axis of its lens, is invalid for prior invention by another under 35 U.S.C. §102(g), since there can be no prior conception or reduction to practice required for prior invention without contemporaneous recognition and appreciation of invention, and since, even if it is assumed that prior art mirror met “varying rate of curvature” limitation, there is no clear and convincing evidence that this feature was recognized and appreciated by alleged prior inventor.

Particular Patents

Particular patents — Designs — Cross-view mirror

D346,357, Englander, automotive mirror, judgment of invalidity reversed.

Particular Patents

Particular patents — General and mechanical — Cross-view mirror

5,589,984, Schmidt and Hutchinson, oval elliptical mirror, judgment of invalidity reversed.

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Case History and Disposition

Appeal from the U.S. District Court for the Eastern District of New York, Sifton, S.J.

Action by Rosco Inc. against Mirror Lite Co. for design patent infringement, inequitable procurement of utility patent, and violation of Lanham Act's Section 43(a), 15 U.S.C. §1125(a). Plaintiff appeals from judgment for defendant on plaintiff's claims, and defendant cross-appeals from judgment holding its patent invalid. Affirmed in part, reversed in part, vacated in part, and remanded.

Attorneys:

Alfred R. Fabricant and Max Moskowitz, of Ostrolenk, Faber, Gerb & Soffen, New York, N.Y., for plaintiff-appellant.

John A. Artz, John S. Artz, and Robert P. Renke, of Artz & Artz, Southfield, Minn., for defendant/cross-appellant

Judge:

Before Lourie, circuit judge, Plager, senior circuit judge, and Dyk, circuit judge.

Opinion Text

Opinion By:

Dyk, J.

Rosco, Inc. ("Rosco") appeals the decision of the United States District Court for the Eastern District of New York finding Rosco's design patent, United States Design Patent No. 346,357 ("the '357 patent"), invalid as functional and obvious, finding that Rosco abandoned its claim that Mirror Lite Company ("Mirror Lite") inequitably procured its utility patent, United States Patent No. 5,589,984 ("the '984 patent"), and rejecting Rosco's claims under 15 U.S.C. §1125(a) of tortious interference with business relations, misrepresentation, and common law trademark infringement. *Rosco, Inc. v. Mirror Lite Co.*, 139 F.Supp.2d 287 (E.D.N.Y. 2001). Mirror Lite cross-appeals the district court's decision that the claims of the '984 patent are invalid. Because the district court erred in finding the '357 patent invalid as functional and obvious; finding the claims of the '984 patent invalid under 35 U.S.C. §§ 102(e) and 102(g); and finding that Rosco abandoned its inequitable conduct claims, we reverse in part, vacate in part, and remand. On remand, the district court should make findings and conclusions on all relevant issues as required by Federal Rule of Civil Procedure 52. Fed. R. Civ. P. 52. We affirm the district court's rejection of Rosco's claims under 15 U.S.C. §1125(a) of misrepresentation and common law trademark infringement.

BACKGROUND

Rosco and Mirror Lite are competitors in the school bus mirror market. This dispute involves "cross-view" mirrors, which are convex, three-dimensional, curved surface mirrors mounted on the front fender of a school bus, enabling the bus driver to view the front and passenger side of a school bus. Rosco filed a complaint on November 19, 1996, and amended the complaint on December 27, 1996 (the "Rosco I case"). A second civil action was subsequently filed by Rosco in October 1999 (the "Rosco II case"). Mirror Lite asserted a counterclaim in the second action. The two cases were consolidated.

Each party owns a patent that it alleged was infringed by the other. Rosco raised a variety of other claims.

1. Rosco's '357 Design Patent

Rosco's '357 design patent relates to an oval, highly convex cross-view mirror with a black, flat metal backing. Rosco applied for the patent on April 14, 1992, and the patent issued on April 26, 1994. Rosco alleged that Mirror Lite infringed the '357 design patent. Mirror Lite argued that the '357 design patent was invalid as functional and therefore was not infringed.

2. Mirror Lite's '984 Utility Patent

Mirror Lite's '984 utility patent relates to an oval cross-view mirror with a varying radius of curvature along the major axis of the convex ellipsoid mirror lens. Mirror Lite filed the parent application that led to the '984 patent on September 9, 1992. The '984 patent issued on December 31, 1996. Rosco requested declaratory judgment that all claims of the '984 patent were invalid as

anticipated under 35 U.S.C. §102(a), invalid for failure to name the true inventor under 35 U.S.C. § 102(f), invalid as previously invented by another under 35 U.S.C. §102(g), and unenforceable due to Mirror Lite's inequitable conduct in procuring the patent.¹ Mirror Lite counterclaimed that Rosco infringed the '984 patent.

3. Rosco's Other Claims

Rosco also alleged that Mirror Lite: engaged in tortious interference with business relations by procuring the '984 patent through

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inequitable conduct; engaged in misrepresentation by publishing disparaging statements about Rosco's mirrors; and engaged in common law trademark infringement by using the marks "Eagle Eye" and "Mini Eagle Eye" to compete with Rosco's "Hawk Eye" and "Mini Hawk Eye" products.

In the Rosco I case, Mirror Lite moved for summary judgment on all claims, and the district court granted summary judgment as to Rosco's claim of tortious interference with business relations. *Rosco*, 139 F.Supp.2d at 294-95. The court denied Rosco's motion for reconsideration on August 19, 1999. *Id.* However, the court later effectively granted reconsideration and reinstated the claim of tortious interference with business relations. *Id.* at 304 n.14.

After a bench trial, the district court: found the '357 design patent invalid as functional and obvious under 35 U.S.C. § 103; found the claims of the '984 patent invalid under 35 U.S.C. §§102(e) and 102(g); did not reach Rosco's claim for design patent infringement because it found the '357 patent invalid; did not reach Mirror Lite's claim of patent infringement because it found the '984 patent claims invalid; did not address the validity of the '984 patent under 35 U.S.C. §§102(a), 102(f), and 103; found that Rosco abandoned its inequitable conduct claims; and rejected Rosco's claims of misrepresentation and common law trademark infringement.

The parties timely appealed. We have jurisdiction under 28 U.S.C. §1295(a)(1).

DISCUSSION

This case presents an example of the need for clear findings of fact and conclusions of law. Federal Rule of Civil Procedure 52(a) requires that "[i]n all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon." Fed. R. Civ. P. 52(a). We have noted the importance of compliance with these requirements, recognizing that one of the purposes of Rule 52(a) is to "provide the appellate court with an adequate basis for review." *Gechter v. Davidson*, 116 F.3d 1454, 1458, 43 USPQ2d 1030, 1033 (Fed. Cir. 1997); see also *Pretty Punch Shoppettes, Inc. v. Hauk*, 844 F.2d 782, 784, 6 USPQ2d 1563, 1565 (Fed. Cir. 1988) ("[T]he trial court must provide sufficient factual findings such that we may meaningfully review the merits of its order."). Here, the district court failed in several instances to make sufficient findings of fact and conclusions of law to provide the necessary predicate for judicial review.

We note also that the parties in this case have made prolix, confusing, and contentious arguments, which no doubt made it particularly difficult for the district court to address the

issues with clarity and precision. We trust that, on remand, counsel will provide the necessary assistance to the district court by appropriately narrowing the issues and coherently explaining their respective positions.

I Rosco's '357 Design Patent

"A patent shall be presumed valid." 35 U.S.C. §282 (2000). To overcome this presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036, 59 USPQ2d 1139, 1142-43 (Fed. Cir. 2001), *cert. denied*, 122 S. Ct. 1196 (2002) (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984)).

Rosco's '357 design patent shows a highly convex, curved-surface, three-dimensional oval mirror with a black, flat metal backing. In May 1992, Rosco began manufacturing the mirror of the '357 patent under the name "Eagle Eye."

Rosco alleged that Mirror Lite infringed the '357 patent by manufacturing and selling a duplicate of Rosco's mirror under the name "Hawk Eye." Mirror Lite argued that the '357 patent was invalid as functional. The district court found the '357 design patent invalid as functional. *Rosco*, 139 F.Supp.2d at 296.

We apply a stringent standard for invalidating a design patent on grounds of functionality: the design of a useful article is deemed functional where "the appearance of the claimed design is 'dictated by' the use or purpose of the article." *L.A. Gear, Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1123, 25 USPQ2d 1913, 1917 (Fed. Cir. 1993) (citing *In re Carletti*, 328 F.2d 1020, 1022, 140 USPQ 653, 654 (CCPA 1964)). "[T]he design must not be governed solely by function, *i.e.*, that this is not the only possible form of the article that could perform its function." *Seiko Epson Corp. v. Nu-Kote Int'l, Inc.*, 190 F.3d 1360, 1368, 52 USPQ2d 1011, 1017 (Fed. Cir.

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1999). "When there are several ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose." *L.A. Gear*, 988 F.2d at 1123, 25 USPQ2d at 1917 (citations omitted). That is, if other designs could produce the same or similar functional capabilities, the design of the article in question is likely ornamental, not functional. Invalidity of a design patent claim must be established by clear and convincing evidence. *Id.*

The district court found that because the mirror's oval shape, the asserted point of novelty of the '357 patent, "of necessity dictates its function," the '357 patent was invalid as functional.² *Rosco*, 139 F.Supp.2d at 296. The court based its determination of functionality on its findings that the mirror of the '357 patent offered a unique field of view (when compared to Mirror Lite's Bus Boy mirror); that Rosco represented to the Patent and Trademark Office that its mirror provided a superb field of view; and that Rosco marketed the mirror of the '357 patent as more "aerodynamic" than other cross-view mirrors. *Id.*

[1] The mere fact that the invention claimed in the design patent exhibited a superior field of view over a single predecessor mirror (here, the Bus Boy) does not establish that the design was

"dictated by" functional considerations, as required by *L.A. Gear*. The record indeed reflects that other mirrors that have non-oval shapes also offer that particular field of view. Similarly, nothing in the record connects the oval shape of the patented design with aerodynamics, and the record shows that other non-oval shaped mirrors have the same aerodynamic effect.

Mirror Lite has not shown by clear and convincing evidence that there are no designs, other than the one shown in Rosco's '357 patent, that have the same functional capabilities as Rosco's oval mirror. Under these circumstances it cannot be said that the claimed design of the '357 patent was dictated by functional considerations. We reverse the district court and hold that the '357 patent claim was not shown to be invalid on functionality grounds.

The district court in a footnote further found the '357 patent claim invalid as obvious, stating simply that "the '357 Patent is invalid as obvious." *Rosco*, 139 F.Supp.2d at 296 n.5. No findings to support this holding of obviousness were made. A finding of obviousness cannot be made without determining whether the invalidating prior art shows or renders obvious the ornamental features of the claimed design. *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1404, 43 USPQ2d 1641, 1646 (Fed. Cir. 1997).³ Because the district court failed to make the necessary findings as to obviousness, we remand for compliance with Rule 52. Should the district court find the '357 patent not invalid, the issue of whether that patent was infringed would have to be addressed by the district court.

II Mirror Lite's '984 Utility Patent

Mirror Lite's '984 patent claims an oval cross-view mirror with a varying radius of curvature along the major axis of the lens. Rosco sought a declaratory judgment that the '984 patent claims were invalid under 35 U.S.C. §§102 and 103, and that the '984 patent was unenforceable on grounds of inequitable conduct.

The district court found claims 1-3 and 6-8 of the '984 patent invalid under both 35 U.S.C. §102(e) (invalidating claims based on anticipation by an earlier filed United States application) and 35 U.S.C. § 102(g) (invalidating claims based on prior invention "by another"). *Rosco*, 139 F.Supp.2d at 302-03. Independent claim 1 provides:

A mirror assembly, comprising:

(a) a mirror lens having a reflective outer surface and a non-reflective rear surface, the mirror lens comprising a mirror

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body which terminates in an oval perimetral edge, the edge surrounds the reflective surface and the non-reflective surface of the mirror lens, the mirror body being a substantially convex ellipsoid having a major axis and a minor axis which intersects with the major axis, *the major axis having a varying radius of curvature*, which radius decreases from the intersection with the minor axis to the perimetral edge. '984 patent, col. 4, ll. 21-31 (emphasis added). Claim 1 thus requires a "varying radius of curvature" along the major axis of the lens. Rosco argued that if the prior art disclosed the varying radius of curvature, then claim 1 is invalid. It made the same argument with respect to dependent claims 2-3 and 6-8. The district court agreed. *Rosco*, 139 F.Supp.2d at 302.

When determining the validity of the claims of a patent, each claim must be separately

considered:

Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.... The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting invalidity. 35 U.S.C. §282 (2000) (emphasis added). Here, the district court found claims 1-3 and 6-8 of the '984 patent invalid without explicitly addressing and analyzing each claim, apparently addressing only independent claim 1.4 There is no evidence that Mirror Lite conceded that those claims stand or fall with independent claim 1. The district court erred by not separately addressing each claim, and on remand should do so. Because we find that the district court's grounds for finding invalidity are not substantiated, we need not consider the claims individually here.

The district court found that the '357 patent inherently disclosed the invention of the '984 patent under 35 U.S.C. §102(e), such that one skilled in the art would read the '357 patent as disclosing a mirror with varying radius of curvature: "the '357 Patent shows a mirror with a varying radius of curvature based on the inherent nature of such a characteristic." *Rosco*, 139 F.Supp.2d at 301. The district court concluded that "one skilled in the art could produce the results claimed in the '984 Patent simply by practicing the '357 Patent, *i.e.*, the result flows naturally from the express disclosures of the '357 Patent whether or not others are aware of it." *Id.* at 300. In reaching this conclusion, the district court relied on Benjamin Englander's 5 testimony that "Rosco would have preferred to have a mirror that had a constant radius of curvature, ... [but] the vacuum thermoforming process used to manufacture such mirrors of necessity yields a mirror with a varying radius of curvature." *Id.* at 301-02. Noting that "[t]his evidence was not contradicted at trial," the court concluded that "anyone practicing the '357 patent by attempting to manufacture it would, on the uncontradicted evidence at trial, come up with a mirror with a varying radius of curvature." *Id.* at 301.

[2] We disagree. Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749(Fed. Cir. 1991). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599(Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). The vacuum thermoforming process, however, is not specified in the '357 patent. Thus, the question is not whether the manufacture of the mirror using this process inherently results in a varying radius of curvature along the major axis, but whether one skilled in the art would read the '357 patent as inherently disclosing the invention of the '984 patent, that is, whether one skilled in the art

would read the '357 patent as showing a mirror of varying radius of curvature along the major axis. There is no evidence in the record to support a finding that one skilled in the art would so read the '357 patent. Englander's testimony only purports to establish that mirrors manufactured

using the vacuum thermoforming process yield a varying radius of curvature along the major axis, but does not purport to establish that the mirror of the '357 patent can only be manufactured by that particular process. At oral argument, counsel for Rosco could not identify any evidence that one skilled in the art would read the '357 patent as inherently disclosing a mirror with varying radius of curvature along the major axis. We accordingly reverse the district court's conclusion that the '984 patent is invalid under section 102(e).

[3] The district court also found claims 1-3 and 6-8 of the '984 patent invalid under section 102(g) in view of Rosco's pre-1992 products, finding that Rosco made the invention of the '984 patent before the '984 critical date. A patent is invalid under section 102(g)(2) if "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2) (2000); *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1339, 60 USPQ2d 1519, 1522(Fed. Cir. 2001). Prior invention by another invalidates a claimed invention under section 102(g)(2) if the prior inventor either reduced the invention to practice first, or conceived of the invention first and subsequently reduced the invention to practice. However, "[i]t is well-settled that conception and reduction to practice cannot be established nunc pro tunc. There must be *contemporaneous recognition and appreciation* of the invention . . ." *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614(emphasis in original) (citing *Breen v. Henshaw*, 472 F.2d 1398, 1401, 176 USPQ 519, 521 (CCPA 1973); see also *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341, 60 USPQ2d 1519, 1523(Fed. Cir. 2001) ("[T]here is no conception or reduction to practice where there has been no recognition or appreciation of the existence of the [invention]."). The question is whether Rosco actually recognized and appreciated a mirror with varying radius of curvature along the major axis of the lens. Though the issue is disputed, particularly with regard to trial exhibit 110, we may assume for present purposes that the earlier Rosco product did in fact have a varying radius of curvature along the major axis of the lens. But there is no evidence that this feature of the invention was recognized and appreciated.

At oral argument we requested Rosco's counsel to identify any evidence that, at the time of invention, Rosco recognized that the mirror it designed had a varying radius of curvature along the major axis, even though Rosco intended to design a mirror with *constant* curvature along the major axis that would not distort the images in the mirror lens. Counsel pointed to the testimony of Englander, who was asked: "When you came up with the idea of this oval mirror, did you have any part of your idea, did it relate to this concept of varying curvature?" Englander answered: "The varying curvature, in my mind, it was automatic because this is the process of producing these lenses which has to have, by nature, a various curvature." Englander's testimony is self-interested and lacks corroboration. It is well established that a party claiming his own prior inventorship must proffer evidence corroborating his testimony. *Sandt Techs. Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350, 60 USPQ2d 1091, 1094(Fed. Cir. 2001). Englander's testimony is insufficient to constitute clear and convincing evidence that Rosco conceived the invention of the '984 patent before the '984 critical date. We therefore reverse the district court's conclusion that the '984 patent is invalid under section 102(g).

The district court did not decide whether the '984 patent was invalid under sections 102(a), 102(f), or 103, stating that "[s]ince the '984 Patent is invalid under 35 U.S.C. §102(e) and (g), there is no need to consider claims of its invalidity under 35 U.S.C. §§102(a), (f), or 103." *Rosco*, 139 F.Supp.2d at 303 n.13. On remand, the district court should analyze the validity of each claim and should consider validity under sections 102(a), 102(f), and 103.

Finally, the district court rejected Rosco's claim that the '984 patent was unenforceable for inequitable conduct, stating that "Rosco is not entitled to judgment that the '984 patent was inequitably procured." *Rosco, Inc. v. Mirror Lite Co.*, No. CV-96-5658 and CV-99-6211, at 2 (E.D.N.Y. Feb. 21, 2001) (final judgment). The district court made no findings

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or conclusions supporting this result, and did not expressly consider this claim.⁶ Again we hold that a remand is required for necessary findings and conclusions as to each claim.

If on remand the district court finds any of the '984 patent claims not invalid and not unenforceable, the issue of whether those claims were infringed would have to be addressed by the district court.

III Rosco's Tortious Interference Claim

Rosco stated a claim under 15 U.S.C. §1125(a) for tortious interference with business relationships based on Mirror Lite's alleged inequitable conduct in securing the '984 patent. [A11]. In a footnote, the district court rejected this claim on the ground that it had been abandoned:

[T]he Court informed counsel for both parties that the summary judgment opinion ... did not dispose of Rosco's claim of tortious interference with business relations ... and invited the parties to submit briefing on this issue. Rosco has not pursued this cause of action at all in either of its two post-trial briefs. Therefore, the Court must consider that Rosco has abandoned this cause of action. *Rosco*, 139 F.Supp.2d at 304 n.14. At oral argument Mirror Lite, with commendable candor, agreed that this claim had not been abandoned, because Rosco had in fact briefed the issue in its post-trial brief. We agree, and remand for findings and conclusions relating to this claim based on the record established at trial.

IV Rosco's Misrepresentation Claim

The district court dismissed on summary judgment Rosco's claim that Mirror Lite engaged in unfair competition under 15 U.S.C. §1125(a) by publishing disparaging statements about Rosco's oval mirror, *Rosco, Inc. v. Mirror Lite Co.*, No. CV-96-5658, at 30 (E.D.N.Y. June 2, 1999) (order granting summary judgment in part) and denied reconsideration. Rosco alleged that Mirror Lite misrepresented Rosco's oval mirror to consumers by publishing various statements, such as that Rosco's mirror did not comply with federal safety standards and that school bus owners must replace their mirrors with mirrors of "identical appearance" to comply with federal safety standards. To establish misrepresentation under 15 U.S.C. § 1125(a), a plaintiff must show that the statement at issue is either (1) literally false as a factual matter; or (2) although literally true, it is likely to deceive or confuse customers. *Nat'l Basketball Assoc. v. Motorola, Inc.*, 105 F.3d 841, 855, 41 USPQ2d 1585, 1597(2d Cir. 1997). The plaintiff must also prove that the "defendant misrepresented an 'inherent quality or characteristic' of the product." *Nat'l Assoc. of Pharm. Mfrs. v. Ayerst Labs.*, 850 F.2d 904, 917, 7 USPQ2d 1530, 1540 (2d Cir. 1988) (citation omitted).

The district court dismissed Rosco's unfair competition claim after finding these statements "literally true," and that they were not "implicitly false" so as to cause confusion. *Rosco, Inc. v. Mirror Lite Co.*, No. CV-96-5658, at 27-28 (E.D.N.Y. June 2, 1999) (order granting summary

judgment in part). We affirm the district court. Rosco did not offer evidence of clear untruth or implied untruth sufficient to defeat summary judgment. We uphold the district court's grant of summary judgment as to this claim, because there is no genuine issue as to the truth of those statements.

V Rosco's Common Law Trademark Infringement Claim

The district court rejected Rosco's claim that Mirror Lite infringed its "Hawk Eye" and "Mini Hawk Eye" common law marks in violation of 15 U.S.C. § 1125(a): "Rosco has produced no evidence in the form of consumer surveys, advertising expenditure, or unsolicited media coverage that 'Hawk Eye' and 'Mini Hawk Eye' have attained secondary meaning. Nor has Rosco established a likelihood of confusion, given the sophistication of the purchasers in the school bus mirror market." 7 *Rosco*, 139 F.Supp.2d at 303-04.

Rosco asserted its claim under 15 U.S.C. §1125(a), section 43(a) of the Lanham Act. Unregistered marks receive essentially the same protection as registered marks: "[T]he Court interprets this section [§43(a)] as having

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created a federal cause of action for infringement of unregistered trademark or trade dress and concludes that such a mark or trade dress should receive essentially the same protection as those that are registered." *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 776 [23 USPQ2d 1081] (1992) (Stevens, J., concurring). McCarthy notes: "When section 43(a) is used as a federal vehicle for assertion of traditional claims of infringement of trademarks, ... the courts have used as substantive law the traditional rules of trademarks and unfair competition law," and concludes that "the test of liability is likelihood of confusion." 4 *McCarthy on Trademarks and Unfair Competition* §27:18 at 27-32 (4th ed. 2002). See also *New West Corp. v. NYM Co. of Cal.*, 595 F.2d 1194, 1201, 202 USPQ 643, 649(9th Cir. 1979) ("[U]nder [§43(a)] the ultimate test is whether the public is likely to be deceived or confused by the similarity of the marks. ... Whether we call the violation infringement, unfair competition or false designation of origin, the test is identical—is there a 'likelihood of confusion'?).

To prevail on a claim for common law trademark infringement under section 1125(a), a party must show likelihood of confusion. This is required by the statute itself: section 1125(a) is triggered by a use that "is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association" of the user with the senior user. 15 U.S.C. §1125(a) (2000). Rosco does not challenge the district court's finding that it failed to show likelihood of confusion.

Because Rosco did not show likelihood of confusion, we affirm the district court's denial of this claim. We need not address the district court's alternative ground for rejecting this claim, *i.e.*, that Rosco failed to establish secondary meaning.⁸

Finally, we have considered Mirror Lite's procedural objections and find them to be without merit.

CONCLUSION

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On remand, the following issues should be addressed on the basis of the existing trial record:

- 1) whether Mirror Lite has shown by clear and convincing evidence that Rosco's '357 design patent is invalid under 35 U.S.C. §103;
- 2) whether Rosco has shown by preponderant evidence that Mirror Lite infringed (if valid) Rosco's '357 design patent;
- 3) whether Rosco has shown by clear and convincing evidence that Mirror Lite's '984 patent is invalid under 35 U.S.C. §§102(a), 102(f), and 103, considering each claim separately;
- 4) whether Rosco has shown by clear and convincing evidence that Mirror Lite's '984 patent is unenforceable due to inequitable conduct;
- 5) whether Mirror Lite has shown by preponderant evidence that Rosco infringed any valid claim of its '984 patent (if those claims are valid and enforceable); and
- 6) whether Rosco has shown that Mirror Lite engaged in tortious interference with business relations through inequitable conduct in procuring the '984 patent.

COSTS

No costs.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED.

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Footnotes

1 The district court deemed Rosco's complaint amended to add claims of patent invalidity under 35 U.S.C. §102(e) (inherently anticipated by prior art) and 35 U.S.C. §103 (invalid as obvious). *Rosco*, 139 F.Supp.2d at 300.

2 The district court's finding in this respect appears to be inconsistent with its earlier summary judgment decision, in which it noted: "A review of the other cross-over mirrors on the market reveals that several different styles of cross-over mirrors exist It cannot be said that the oval shape and flat backing are dictated by function." *Rosco, Inc. v. Mirror Lite Co.*, No. CV-96-5658, at 15 (E.D.N.Y. June 2, 1999) (order granting summary judgment in part).

3 See *In re Haruna*, 249 F.3d 1327, 1335, 58 USPQ2d 1517, 1522 (Fed. Cir. 2001) ("The obviousness of a design 'is determined by ascertaining whether the applicable prior art contains any suggestion or motivation for making the modifications in the design of the prior art article in order to produce the claimed design.'" (quoting *Hupp v. Siroflex of Am., Inc.*, 122 F.3d 1456, 1462, 43 USPQ2d 1887, 1891 (Fed. Cir. 1997)); *Durling v. Spectrum Furniture Co.*, 101 F.3d 100, 103, 40 USPQ2d 1788, 1790 (Fed. Cir. 1996) (The inquiry under section 103 is "whether the claimed design would have been obvious to a designer of ordinary skill who designs articles of the type involved.")).

4 Also, the district court failed to explicitly mention claims 4, 5, and 9, instead concluding: "the

'984 patent is declared invalid.” *Rosco*, 139 F.Supp.2d at 303. On remand, the district court should consider these claims.

5 Rosco is a closely held corporation owned by the Englander family: Solomon Englander, Rosco’s president (father); Benjamin Englander, Rosco’s vice president of engineering (son); Daniel Englander, Rosco’s vice president of finance (son); and Gertrude Englander (mother).

6 We reject Mirror Lite’s argument that the inequitable conduct issue was not properly raised.

7 While Rosco’s “Hawk Eye” mark was apparently a registered trademark, Rosco asserted claims under 15 U.S.C. §1125(a), which protects unregistered marks. We therefore do not understand Rosco to have asserted a claim of trademark infringement.

8 Three other claims under 15 U.S.C. §1125 were originally asserted in the district court: Rosco alleged that Mirror Lite infringed its alleged common law trademark rights in its product numbering system; infringed the trade dress of its “Hawk Eye” mirrors; and infringed its alleged common law trademark rights in the “Eagle Eye” mark. It is not clear whether Rosco’s common law trademark claim as to its product numbering system is at issue on appeal, but we find no error with the district court’s rejection of that claim. As for the trade dress claim, the district court concluded that Rosco abandoned its trade dress claim in light of the Supreme Court’s decision in *Wal-Mart Stores, Inc. v. Samara Brothers, Inc.*, 529 U.S. 205, 216 [54 USPQ2d 1065] (2000). Rosco does not argue to the contrary. Finally, the district court found that Rosco abandoned its claim that its alleged common law trademark rights in the “Eagle Eye” mark were infringed. We do not understand this ruling to be challenged on appeal.

**- End of Case -
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Continental Can Co. USA Inc. v. Monsanto Co. (CA FC) 20 USPQ2d 1746

Continental Can Co. USA Inc. v. Monsanto Co.□

U.S. Court of Appeals Federal Circuit
20 USPQ2d 1746

Decided November 13, 1991
No. 90-1328

Headnotes

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure - Summary judgment - Patents (§ 410.3303)

Summary judgment is as available in patent cases as in other areas of litigation and can facilitate disposition of legally meritless suits, but improvident grant of summary judgment can prolong litigation and increase its burdens, especially in patent disputes in which patent property is wasting asset.

PATENTS

2. Patentability/Validity - Anticipation - In general (§ 115.0701)

Anticipation under 35 USC 102 cannot be found if more than one reference is required to establish unpatentability of claimed invention; rather, validity in such case is determined pursuant to 35 USC 103.

3. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Patent construction - Claims - Defining terms (§ 125.1305)

Federal district court erred by ruling, on summary judgment, that claims for patented bottle were anticipated by prior art, since court erred in its construction of claim term "hollow," and since disputed issue of fact exists as to whether injection blow molding process necessarily produced "hollow" ribs in prior art base structure, as term "hollow" is used in patent.

4. Patentability/Validity - Anticipation - Prior sale - In general (§ 115.0707.01)

"On sale" bar of 35 USC 102(b) does not arise simply because intended customer was participating in development and testing, but rather all circumstances concerning relationship between patentee and customer must be considered in light of public policy underlying Section 102(b); thus, federal district court erred in determining that bottle was "on sale," in view of evidence showing that bottle was part of terminated development project that never bore commercial fruit and was cloaked in confidentiality.

5. Patentability/Validity - Obviousness - Combining references (§ 115.0905)

Federal district court erred by ruling, on summary judgment, that claimed bottom structure for plastic container was obvious, since, drawing all reasonable inferences in favor of patentee, it has not been established that person skilled in art would be motivated to select and combine features from each prior art source to make patented base.

6. Patentability/Validity - Obviousness - Secondary considerations generally (§ 115.0907)

Differences between patented invention and prior art which may appear technologically minor nonetheless can have practical impact, particularly in crowded field, and in such case objective indicia, such as commercial success, or filling existing need, illuminate technological and commercial environment of inventor, and aid in understanding state of art at time invention was made.

7. Patentability/Validity - Obviousness - Commercial success (§ 115.0908)

Patented invention need not be solely responsible for commercial success in order for this factor to be given appropriate weight.

Particular patents - General and mechanical - Plastic bottle

4,108,324, Krishnajumar, Roy, Pocock, Das, and Mahajan, ribbed beverage bottle structure for plastic container created by plastic hot-fill, summary judgment of invalidity vacated in part, reversed in part, and remanded.

Case History and Disposition:

Appeal from the U.S. District Court for the Southern District of Ohio, Spiegel, J.; 11 USPQ2d 1761 .

Patent infringement action brought by Continental Can Co. USA Inc. and Continental Pet Technologies Inc. against Monsanto Co., Hoover Universal Inc., and Johnson Controls Inc. From federal district court decision entering summary judgment in favor of defendants, plaintiffs appeal. Vacated in part, reversed in part, and remanded.

Attorneys:

Eugene F. Friedman, Chicago, Ill. (Edwin C. Thomas, III and David M. Novak, of Bell, Boyd & Lloyd, Chicago; Kurt L. Grossman, of Wood, Herron & Evans, Cincinnati, Ohio, with him on brief), for plaintiff-appellants.

Henry J. Renk, New York, N.Y. (Lawrence F. Scinto and Bruce C. Haas, of Fitzpatrick, Cella, Harper & Scinto, New York; Jacob K. Stein and Deborah DeLong, of Thompson, Hine & Flory, Cincinnati, Ohio; Lawrence L. Limpus, St. Louis, Mo., and Edward L. Levine, Milwaukee, Wis., with him on brief), for defendants-appellees.

Judge:

Before Newman, Archer, and Rader, circuit judges.

Opinion Text

Opinion By:

Newman, J.

Continental Can Company USA and Continental PET Technologies (collectively "Continental") appeal the partial summary judgment of the United States District Court for the Southern District of Ohio, holding that United States Patent No. 4,108,324 (the Conobase or '324 patent) is invalid. 1 Final judgment was entered on this issue, for the purpose of appeal.

Summary Judgment

An issue may be decided on motion for summary judgment when there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325-26 (1986); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1571, 18 USPQ2d 1001, 1005 (Fed. Cir. 1991). The movant's burden is to show that no fact material to the issue is in dispute, that even if all material factual inferences are drawn in favor of the

non-movant the movant is entitled to judgment as a matter of law. *Id.* Summary judgment is as available in patent cases as in other areas of litigation. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 778-79, 218 USPQ 673, 675 (Fed. Cir. 1983)

The purpose of the summary process is to avoid a clearly unnecessary trial, *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); it is not designed to substitute lawyers' advocacy for evidence, or affidavits for examination before the fact-finder, when there is a genuine issue for trial. As stated in *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 176 (1970) (Black, J., concurring), "[t]he right to confront, cross-examine and impeach adverse witnesses is one of the most fundamental rights sought to be preserved by the Seventh Amendment". See also *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 473 (1962).

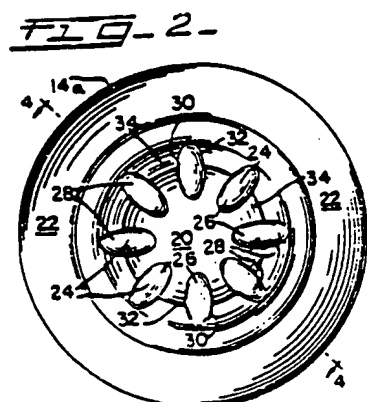
[1] While facilitating the disposition of legally meritless suits, when summary judgment is improvidently granted the effect is to prolong litigation and increase its burdens. This is of particular concern in patent disputes, where the patent property is a wasting asset, and justice is ill served by delay in final resolution. In the case at bar, although some issues could be resolved on the law and undisputed facts, other issues require trial.

The Patented Invention

The '324 patent, entitled "Ribbed Bottom Structure for Plastic Container", inventors Suppayan M. Krishnakumar, Siegfried S. Roy, John F. E. Pocock, Salil K. Das, and Gautam K. Mahajan, is directed to a plastic bottle whose bottom structure has sufficient flexibility to impart improved impact resistance, combined with sufficient rigidity to resist deformation under internal pressure. The patented bottle is said to provide a superior combination of these properties. The bottom structure is illustrated as follows:

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Fig. 2



Claim 1 is the broadest claim of the '324 patent:

1. A container having a sidewall and a bottom structure closing the container at an end portion of the sidewall,
the outer surface of the bottom structure comprising a central concavity,
a convex heel surrounding the concavity and merging therewith and with the sidewall end portion, the lowermost points of the heel lying in a common plane,

and a plurality of ribs interrupting the outer surface of the concavity and distributed in a symmetrical array, each rib extending longitudinally in the direction of the heel and downwardly from an inner portion of the concavity, whereby the outer end portion of each rib is lower than the inner end portion thereof, characterized by the feature that the ribs are hollow.

Claims 2 through 5 include additional limitations, described as contributing to the structure's rigidity, flexibility, or both. Claim 2 specifies the ratios of thickness of the walls of the bottom structure to the thickness of the sidewall end portions. Claim 3 specifies that the margins of each rib merge smoothly with adjacent portions of the bottom structure. Claim 4 specifies that each rib is convex relative to the bottom structure. Claim 5 specifies that each rib is of fusiform (a gently tapered shape at the ends) configuration. Each claim carries an independent presumption of validity, 35 U.S.C. § 282, and stands or falls independent of the other claims. *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 487 [24 USPQ 308] (1935).

Continental brought suit for patent infringement against Monsanto Company and Monsanto's successor in this business, Hoover Universal, Inc. and Hoover's parent company, Johnson Controls (collectively "Monsanto"). Monsanto moved for partial summary judgment based on issues of validity under 35 U.S.C. §§ 102 and 103.

I

35 U.S.C. § 102(a)

The statutory requirement that a patented invention be "new" is tested in accordance with 35 U.S.C. § 102(a), which provides that:

§ 102. A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent....

The district court found that all the claims of the '324 patent were anticipated by U.S. Patent No. 3,468,443 (the Marcus patent). We conclude that the district court erred in claim interpretation, and also found disputed facts adversely to the nonmovant, thus inappropriately deciding the issue summarily.

[2] Anticipation under § 102(a) requires that the identical invention that is claimed was previously known to others and thus is not new. *Scripps Clinic*, 927 F.2d at 1576, 18 USPQ2d at 1010; *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777-78 (Fed. Cir. 1985); *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984). When more than one reference is required to establish unpatentability of the claimed invention anticipation under § 102 can not be found, and validity is determined in terms of § 103.

It was Monsanto's burden to show that every element of the several claims of the '324 patent was identically described in the asserted anticipating reference, the Marcus patent. The district court focused on the term "characterized by the feature that the ribs are hollow", which limits all of the '324 patent claims. Continental argues that the district court incorrectly construed this term, as a matter of law, and that the Marcus patent shows ribs that are not hollow, as that term is used in the '324 patent. Continental also points to other differences between the '324 claims and the description in the Marcus patent.

The Marcus patent rib structure is illustrated in Figure 5 and in cross-section in Figure 6:

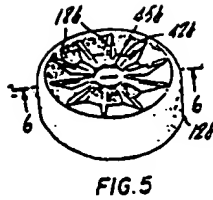


FIG. 5

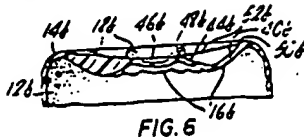


FIG. 6

The Marcus patent does not state that its ribs are "hollow", or use a similar term. Continental's witnesses testified by deposition that the Marcus patent shows solid, not hollow, ribs. A witness (Adomaitis) had stated in an internal memorandum written at Continental in 1969, well before this litigation arose, that "the ribs of their [Marcus] web can be made of solid beams only." Another witness, '324 co-inventor Pocock, testified that:

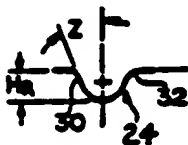
It seems evident to me that he [Marcus] was trying to produce some kind of container integrity by the production of essentially solid ribs on the bottom of the bottle. It seems to go to great length here to illustrate them as such.

Krishnakumar, another co-inventor, testified that it "is very obvious the ribs are shown solid", and that Figures 5 and 6 as well as Figures 7 through 12 of the Marcus patent all show solid ribs. However, Marcus, testifying for Monsanto, testified that his ribs were hollow, and that conventional blow molding would inherently produce hollow ribs.

The district court defined "hollow" as meaning that "the inside contour of the ribs generally follows the outside contour thereof", a definition on which the parties agreed. *Continental*, 11 USPQ2d at 1764. See the court's opinion, 11 USPQ2d at 1764-68, for various sketches made by the witnesses. Continental states that the district court erred in construing "hollow", and that the phrase "characterized by the feature that the ribs are hollow" must be construed in terms of the patent in which it appears. See, e.g., *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1021, 4 USPQ2d 1283, 1286 (Fed. Cir. 1987). The '324 patent explicitly distinguished the Marcus teachings, stating that the '324 ribs are, unlike Marcus, not filled with plastic. The '324 specification uses the term "hollow", as do the prosecution history and the claims, for this purpose. The '324 patent's usage of "hollow" is illustrated in rib cross-section in Figure 5A:

Fig. 5A

FIG. 5A



The Marcus patent's rib structure thus was explicitly differentiated by the term "hollow" as used in the '324 specification, drawings, and prosecution history. Since the claim term must be

construed as used by the patentee, the district court erred in its construction of the '324 claim term "hollow". On correct claim construction, the factual question of anticipation must be decided.

Monsanto's argument is that hollow ribs were inherently produced by Marcus. Monsanto thus argues that anticipation lies because the Marcus patent's ribs are "inherently" hollow, regardless of how they are shown in the Marcus patent. Monsanto argues that because the Marcus ribs are formed by injection blow molding, which is the same process described for the Conobase '324 ribs, hollow ribs are inherently disclosed in the Marcus patent.

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)) provides:

Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

This modest flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological

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facts are known to those in the field of the invention, albeit not known to judges. It is not, however, a substitute for determination of patentability in terms of § 103.

[3] Continental does not dispute the applicability of the injection blow molding process. However, Continental disputes the material of fact of whether this process necessarily produced "hollow" ribs in the Marcus base structure, as the term "hollow" is used in the '324 patent. Resolution of this disputed fact adversely to Continental was improper on summary judgment. The grant of summary judgment of anticipation under § 102(a) is vacated. The issue requires trial.

II

35 U.S.C. § 102(b)

The district court also held that the Marcus bottle was on sale, 35 U.S.C. § 102(b). Section 102(b) bars entitlement to a patent when:

(b) the invention was ... in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States....

The Marcus bottle was developed some ten years before the filing date of the '324 patent, during a project wherein Marcus' employer, Admiral Plastics or APL Corporation, entered into agreements with the Coca-Cola Company for the development of a suitable plastic bottle. The agreements provided that Admiral Plastics would make and Coca-Cola would test the bottles, and that if a satisfactory bottle was developed it would be manufactured by Admiral and purchased by Coca-Cola. Minimum commercial quantities and maximum commercial prices were stated in an agreement, and costs were a matter of discussion. Admiral produced a variety

of bottle shapes, including the Marcus bottle. The project was terminated after about two years, because the "mechanical performance" requirements were not met as Coca-Cola wrote at the time.

[4] The district court reasoned that this project "called for the eventual marketing of the Marcus bottles once all technical difficulties were resolved", *Continental*, 11 USPQ2d at 1766, and on this basis held that the Marcus bottles were on sale. This holding was in error, for the "on sale" bar of § 102(b) does not arise simply because the intended customer was participating in development and testing. See *Great Northern Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 164-65, 228 USPQ 356, 358 (Fed. Cir. 1986). In *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1563-65, 4 USPQ2D 1210, 1213-15 (Fed. Cir. 1987), this court summarized various factors pertinent to the "on sale" bar when there is an issue concerning the relationship between the patentee and the customer: for example, whether there was a need for testing by other than the patentee; the amount of control exercised; the stage of development of the invention; whether payments were made and the basis thereof; whether confidentiality was required; and whether technological changes were made. All of the circumstances attending the relationship must be considered in light of the public policy underlying § 102(b). *UMC Electronics Co. v. United States*, 816 F.2d 647, 656, 2 USPQ2d 1465, 1471-72 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988).

The district court acknowledged that all technical difficulties were not resolved and that no sales were ever made. Although Admiral Plastics' hope was surely commercial sales, and the record shows that prices and quantities were discussed, this does not of itself place the subject matter "on sale" in the sense of § 102(b). The Marcus bottle was part of a terminated development project that never bore commercial fruit and was cloaked in confidentiality. While the line is not always bright between development and being on sale, see generally *UMC Electronics, supra*, in this case the line was not crossed. The "on sale" bar is measured by "the time the public came into possession of the invention", *id.* at 655, 2 USPQ2d at 1471 (quoting *In re Foster*, 343 F.2d 980, 987-88, 145 USPQ 166, 173 (CCPA 1965), *cert. denied*, 383 U.S. 966 [149 USPQ 906] (1966) ("What starts the period running is clearly the availability of the invention to the public through the categories of disclosure enumerated in 102(b). ..." (emphasis in original))). We conclude that the district court erred in holding that the circumstances that here existed placed the Marcus bottles "on sale" in terms of § 102(b). We therefore reverse and direct that on remand judgment on this issue shall be entered in favor of Continental, as a matter of law.

III

35 U.S.C. § 103

Obviousness, 35 U.S.C. § 103, is reviewed as a legal conclusion based upon underlying facts of four general categories, *viz.* the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill at the time the invention was made, and any objective considerations that may be present. *Gra*

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ham v. John Deere Co., 383 U.S. 1, 17 [148 USPQ 459] (1966); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1137-38, 227 USPQ 543, 547 (Fed. Cir. 1985).

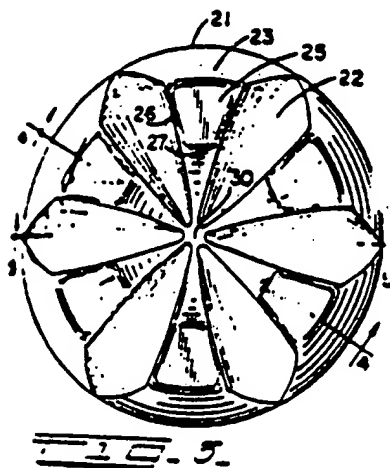
[5] The parties agreed that the scope and content of the prior art was adequately represented by four references: the Marcus patent discussed in Part I *ante*, a patent to Colombo (U.S. Patent No. 3,403,804), and two patents owned by Continental, U.S. Patent No. 3,598,270 (the Petaloid

patent), and No. 3,935,955 (the Decaloid patent). They agreed on little else. In granting summary judgment of invalidity for obviousness, the district court found certain disputed material facts and misapplied certain precepts of law. We conclude that the issue was not amenable to summary resolution. Although it is not entirely clear how the references were combined by the court, we shall review the references briefly, in order to explain our conclusion.

The Petaloid Patent

The district court referred to the deposition testimony of Siegfried Roy, one of the co-inventors of the '324 patent, that the Petaloid base, inverted, was similar to the Conobase. Continental points out that neither Roy nor any other deponent suggested that the Petaloid base could be or should be inverted, or that inversion would provide an improved base structure. In *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) this court held that although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down. Continental points out that the Petaloid description differs in several other ways from the '324 invention. In the '324 structure the outer end of each rib is lower than the inner end, whereas in the Petaloid structure the outer ends of the ribs are higher than the inner ends; that is, the ribs in the Petaloid base extend upward from the center to the sidewall. The Petaloid bottle is supported on feet extending between the ribs, such feet being the locations for stress concentrations. The following drawing is from the Petaloid patent:

Fig. 3



Continental states that the '324 Conobase is not only different, but avoids the stress concentrations of the Petaloid device, thus enhancing impact resistance. Monsanto argues that Continental simply used the Petaloid hollow ribs in combination with the Marcus patent. This requires determination of whether there was something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination, in a way that would produce the '324 structure. See, e.g., *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988). Continental argues that it is not apparent, even with hindsight, how any combination of the Petaloid and Marcus patents or other references lead to the '324 base. The Petaloid patent shows concave ribs that extend all the way to the sidewall, while the Marcus ribs extend "from the heel" toward an annular central ring. The Petaloid base has wide, petal-like, open ribs, while Marcus shows narrow, beam-like ribs.

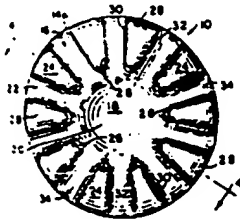
The deposition testimony was in conflict as to the inferences drawn from the references. On this disputed issue, drawing reasonable inferences in favor of the non-movant, it has not been established that one skilled in the art would be motivated to select and combine features from each source in order to make the '324 base. *Interconnect Planning*, 774 F.2d at 1143, 227 USPQ at 551 ("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself").

The Decaloid Patent

The district court also referred to combination of the Decaloid base with the Marcus base. The Decaloid base has ten hollow ribs that extend to the sidewall, and ten feet between the ribs:

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Fig. 2

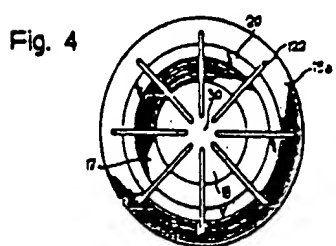


Monsanto does not explain, and we can not discern, how the combination with Marcus would have led a person of ordinary skill to the '324 base. The court's summary holding of obviousness based on these references, separately or in combination, can not be sustained.

The Colombo Patent

The Colombo base, like the Petaloid and Decaloid bases, has hollow ribs that extend to the sidewall, in a still different structure from that of Marcus and also from that of the '324 patent. Colombo describes his ribs as inverted U-shapes, concave, located on the outer surface of the central concavity:

Fig. 4



Again, drawing reasonable factual inferences in favor of Continental, and in the absence of any suggestion or motivation in the prior art as a whole to make a selective combination of the Colombo and Marcus structures along with other changes needed to obtain the '324 structure, summary judgment of obviousness was inappropriate.

The district court found that there was no substantial difference between the '324 invention and the combined teachings of the prior art:

As obviousness can be established on the basis of the combined teachings of references, we think it is clear that simple enhancements of existing prior art, i.e., inverting the '270 petaloid base, do not constitute a substantial difference between the subject matter claimed in the '324 patent and that of the prior art. Thus, the facts of this case reveal no substantial difference between '324 and the prior art. *Continental*, 11 USPQ2d at 1769 (citation omitted). However, as we have discussed, the criterion of § 103 is not whether the differences from the prior art are "simple enhancements", but whether it would have been obvious to make the claimed structure.

Objective Indicia

The district court concluded that the structure in suit is simply a variation on known themes. It is in such circumstance that the objective indicia - the so-called secondary considerations - are most useful to the decision-maker. The significance of a new structure is often better measured in the marketplace than in the courtroom.

[6] Thus when differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light. Such objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made. *See In re Piasecki*, 745 F.2d 1468, 1475, 223 USPQ 785, 790 (Fed. Cir. 1984) (secondary considerations "often establish that an invention appearing to have been obvious in light of the prior art was not" (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39, 218 USPQ 871, 879 (Fed. Cir. 1983))).

Continental licensed the '324 counterpart Japanese patent to a Japanese company, Yoshino, that we are told had been unable to develop a plastic bottle for hot-fill applications. A witness for Toyo Seikan, another Japanese licensee, testified that the Conobase "sustains itself in higher temperatures, and it does not cause buckling after you fill [the bottle]", as compared with previously available plastic bottles. Continental asserts that Monsanto had been unable to develop a satisfactory bottle for hot-fill applications, and had therefore obtained this technology from Yoshino.

[7] The district court acknowledged the commercial success of the Conobase, but stated that "we are not convinced that the conobase *alone* accounts for any of the success." 11 USPQ2d at 1770 (emphasis in original). The court suggested that the commercial success in Japan was due to the market strength of the Japanese licensees, and held that there is no nexus between the merits of the product and its commercial success. It is not necessary, however, that the patented invention be solely responsible for the commercial success, in order for this

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factor to be given weight appropriate to the evidence, along with other pertinent factors. *See generally Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392-94, 7 USPQ2d 1222, 1226-28 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (Fed. Cir. 1984). Monsanto also states that the Conobase is different from the '324 invention, so that even were the Conobase successful, this does not inure to the benefit of the '324 patent. It is apparent that the factual issues surrounding the objective indicia were disputed, and material. In view of the material facts requiring resolution, the issue of obviousness was not properly

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decided on motion for summary judgment. We vacate the grant based on 35 U.S.C. § 103, and remand for trial of this issue and the other issues remaining in the case.

Costs

Costs in favor of Continental.

REVERSED IN PART, VACATED IN PART, and REMANDED

Footnotes

Footnote 1. *Continental Can Co. USA v. Monsanto Co.*, 11 USPQ2d 1761 (S.D. Ohio 1989), *reconsid. denied*, No. C-1-86-1213 (S.D. Ohio Nov. 9, 1989).

- End of Case -

Ex parte Levy (BdPatApp&Int) 17 USPQ2d 1461

Ex parte Levy

**U.S. Patent and Trademark Office, Board of Patent Appeals
and Interferences
17 USPQ2d 1461**

**Decided October 16, 1990
No. 90-1864**

Headnotes

PATENTS

1. Patentability/Validity - Anticipation - Identity of elements (§ 115.0704)

Factual determination of anticipation requires disclosure in single reference of every element of claimed invention, and examiner must identify wherein each and every facet of claimed invention is disclosed in applied reference.

2. Patentability/Validity - In general (§ 115.01)

Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Initial burden of establishing prima facie basis to deny patentability rests upon examiner; examiner, if relying upon theory of inherency, must provide basis in fact and/or technical reasoning to reasonably support determination that allegedly inherent characteristic necessarily flows from teachings of applied prior art.

3. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Examiner erred by rejecting claims for biaxially oriented catheter balloon as anticipated by prior art which does not disclose such biaxially oriented balloon and which has not been shown to be inherently biaxially oriented.

**4. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions
(§ 115.0903.03)**

Examiner erred by rejecting claims for biaxially oriented balloon catheter under 35 USC 103 based upon combined disclosure of two prior art references, one of which was relied upon solely for disclosed use of high viscosity polyethylene terephthalate tubing and the other which was presupposed by examiner to disclose biaxially oriented catheter balloon, since examiner has not established that resulting catheter balloon using high viscosity tubing is biaxially oriented.

Case History and Disposition:

Page 1461

Application of Stanley B. Levy, serial no. 287,234, filed Dec. 21, 1988, which is a division of serial no. 914,108, filed Oct. 1, 1986, now Re. 32,983, granted July 4, 1989; and a reissue of serial no. 510,812, filed July 5, 1983, now patent no. 4,490,421, granted Dec. 25, 1984, for balloon and manufacture thereof. From examiner's rejection of claims 13 through 17 and 25 (James Seidleck, primary

Page 1462

examiner), applicant appeals. Reversed.

Attorneys:

Louis H. Rombach, Wilmington, Del., for appellant.

Judge:

Before Steiner, Tarring, and J. Smith, examiners-in-chief.

Opinion Text

Opinion By:

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the

claims remaining in this application for reissue of U.S. Patent No. 4,490,421.

The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting sufficient pressure to dilate stenotic lesions without rupture of the balloon.

Claims 13 and 25, the only independent claims on appeal, read as follows:

13. *High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).*

25. *High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation catheter balloon.*

The references relied upon by the examiner are:

Wyeth et al. (Wyeth)	3,733,309	May 15, 1973
Schjeldahl et al. (Schjeldahl '989)	4,413,989	Nov. 8, 1983 1
Schjeldahl et al. (Schjeldahl '000)	4,456,000	June 26, 1984 2

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl.

Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. §102.

[1] The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada*, — F.2d —, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Bond*, — F.2d —, 15 USPQ2d 1566 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); *Alco Standard Corp. v. TVA*, 808 F.2d 1490, 1 USPQ2d 1337 (Fed. Cir. 1986); *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley*, 455 F.2d 586, 172 USPQ 524 (CCPA 1972).

Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a *prima facie* basis to defeat the patentability of independent claims 13 and 25 under 35 U.S.C. §102, the examiner is obliged to point out where Schjeldahl discloses a *biaxially oriented* polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon. See, for example, page 5 of the Final Rejection wherein the examiner states he reference clearly teaches a biaxially oriented balloon catheter, and states that it is made by injection blow molding.

See, also, page 5 of the Answer wherein the examiner states arguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is *clearly stated* in the references (emphasis supplied). The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.

It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:

(a) an expander 3 formed *from* a thin, flexible inelastic, high tensile strength, *biaxially oriented* synthetic plastic material

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(column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);

(b) The expander 30 is preferably formed *from* a suitable synthetic plastic material, such as *biaxially oriented* polypropylene, *by an injection blow molding operation* and, as such, is substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in the range of from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);

(c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);

(d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);

(e) the expander 30 is formed *from* a *biaxially oriented* thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);

(f) the expander 82 is preferably formed *from* a suitable synthetic plastic material such as *biaxially oriented polypropylene* or *biaxially oriented polyethylene terephthalate by an injection molding operation* and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and

(g) Apparatus as in claim 1 wherein said non-elastic expander member comprises a longitudinally extending thin, flexible, tubular element *formed from a biaxially oriented* synthetic plastic material surrounding said outer tubular member with opposed ends thereof secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis supplied).

These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon.

According to Schjeldahl, the *starting* material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The *final article*, i.e., the expander or catheter balloon, is *not characterized as biaxially oriented*. Moreover, it would appear to be *undisputed* that the *only* method disclosed by Schjeldahl for transforming the biaxially oriented *starting* plastic into the *final* catheter balloon, i.e., injection blow molding, is *not* capable of producing a biaxially oriented catheter balloon. In fact, it is *undisputed* that injection blow molding would *destroy* the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits V, VI and VIII, 4 which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon. 5

Indeed, the examiner agrees with appellant's position that injection blow molding could *not* produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:

statements that injection blow molding without stretching will not produce a biaxially oriented article are *true ...* (emphasis supplied).

The examiner goes on, in the same sentence, to state:
but since the reference produces a biaxially oriented article, clearly a stretching step must be used.

Again, on page 5 of the Answer, the examiner states:

Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.

The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.

[2] The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests

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upon the examiner. *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); *In re Wilding*, 535 F.2d 631, 190 USPQ 59 (CCPA 1976); *Hansgirk v. Kemmer*, 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden. Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have only a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would not have produced a biaxially oriented balloon and would have destroyed the biaxial orientation of a polymeric starting material.

Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) necessarily means that the catheter balloon is biaxially oriented.

According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are inconsistent with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

the membrane equation used to determine the tensile [sic, tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that

certainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration would be reasonable.

As noted above, the conflicting results obtained by applying the membrane equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired

value," underscore the speculative nature upon which the determination of inherency rests. We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction *necessarily* means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

[3] In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We do not find a sufficient basis to support the determination that Schjeldahl's balloon is *inherently* (necessarily) biaxially oriented. *In re King, supra*; *W.L. Gore & Associates, Inc. v. Garlock, Inc., supra*; *In re Oelrich, supra*; *In re Wilding, supra*; *Hansgirk v. Kemmer, supra*. Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. §102 as anticipated by Schjeldahl is reversed. 6

The Rejection of Claims 13 through 17 under 35 U.S.C. §103 Based upon the Combined Disclosures of Schjeldahl and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; *e.g.*, at least about 0.85.

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It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is *not* predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth *solely* for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic, examiner's] inherency arguments. 7 ... The examiner is not substituting the process of Wyeth et al into Schjeldahl et al since both disclose the same process. 8 Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

[4] We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, *arguendo*, the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. §103 must fall because the examiner has not established that the resulting catheter balloon is biaxially oriented. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. §103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the

paragraph bridging pages 5 and 6 of the Answer, 9 we are constrained to address that issue. There appears to be no dispute that one having ordinary skill in the art would have recognized the desirability of producing a biaxially oriented balloon for use in Schjeldahl's catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, *the technique employed by Wyeth to produce a beverage container*. See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, *Wyeth disagrees*. See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could *not* be used to produce a catheter balloon of the type disclosed by Levy. We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the affidavits of Rydell, Pinchuk and Kaufman, 10 that the known processes for producing

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biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill. 11 Based upon the record before us, it would appear unrealistic to conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a *reasonable expectation* of obtaining a *biaxially oriented* polymeric catheter balloon. *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). The rejection under 35 U.S.C. §103 is also reversed.
REVERSED.

Footnotes

Footnote 1. Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner.

Footnote 2. See footnote 1.

Footnote 3. Schjeldahl characterizes the catheter balloon as an expander.

Footnote 4. Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.

Footnote 5. We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. *In re Weber*, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); *In re Michalek*, 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made of a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the operability of Schjeldahl, but quite relevant to the issue of inherency, *i.e.*, whether the catheter balloon disclosed by Schjeldahl is inherently biaxially

oriented.

Footnote 6. There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000-40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).

Footnote 7. Actually, according to the Final Rejection which is incorporated in the Answer, it is the Examiner's position that it would be *prima facie* obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).

Footnote 8. It is apparent from our reversal of the examiner's rejection under 35 U.S.C. §102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.

Footnote 9. The noted statement provides:

Certainly in the least there was an *invitation* to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).

Footnote 10. We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.

Footnote 11. We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III), wherein it is stated

s a blow molded polymeric article, a bottle and a catheter balloon are equivalent.

See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures - they are both fluid containers.

- End of Case -

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In re Dembiczak ☐

U.S. Court of Appeals Federal Circuit ☐
50 USPQ2d 1614 ☐

Decided April 28, 1999 ☐
No. 98-1498

Headnotes

PATENTS

1. Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Decision rejecting claims in utility application as obvious over combination of prior art references must be reversed, since obviousness analysis in decision is limited to discussion of ways that multiple references can be combined to read on claimed invention, but does not particularly identify any suggestion, teaching, or motivation to combine references, and does not include specific or inferential findings concerning identification of relevant art, level of ordinary skill in art, nature of problem to be solved, or any other factual findings that might support proper obviousness analysis.

2. Patentability/Validity -- Anticipation -- Double patenting (§ 115.0708)

Obviousness-type double patenting may be found between design and utility patents in rare cases, but such rejection is appropriate only if claims of two patents cross-read, meaning that subject matter of claims of patent sought to be invalidated would have been obvious from subject matter of claims of other patent, and vice-versa.

3. Patentability/Validity -- Anticipation -- Double patenting (§ 115.0708)

Applicants' design patents for bag with jack-o'-lantern face would not have been obvious

variants of their pending utility claims directed to trash bag decorated to resemble Halloween pumpkin when filled with trash or leaves, since textual description of "facial indicia" on bag found in claims of utility patent application cannot constitute design reference that is "basically the same as" specific designs claimed in applicants' patentably distinct design patents.

Case History and Disposition:

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Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application of Anita Dembiczak and Benson Zinbarg for utility patent (application serial no. 08/427,732). From decision sustaining rejections of claims in application, applicants appeal. Reversed.

Attorneys:

David P. Gordon and Thomas A. Gallagher, Stamford, Conn., for appellants.

John M. Whealan, associate solicitor, Albin F. Drost, acting solicitor, and David R. Nicholson, associate solicitor, Office of the Solicitor, Arlington, Va., for appellee.

Judge:

Before Mayer, chief judge, and Michel and Clevenger, circuit judges.

Opinion Text

Opinion By:

Clevenger, J.

Anita Dembiczak and Benson Zinbarg appeal the rejection, upheld by the Board of Patent Appeals and Interferences, of all pending claims in their Application No. 08/427,732. *See Ex Parte Dembiczak*, No. 96-2648, slip op. at 43 (May 14, 1998). Because the Board erred in sustaining rejections of the pending claims as obvious under 35 U.S.C. Section 103(a) (Supp. 1998), and for obviousness-type double patenting, we reverse.

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I

The invention at issue in this case is, generally speaking, a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern. As the inventors, Anita Dembiczak and Benson Zinbarg (collectively, "Dembiczak") note, the invention solves the long-standing problem of unsightly trash bags placed on the curbs of America, and, by fortuitous happenstance, allows users to express their whimsical or festive nature while properly storing garbage, leaves, or other household debris awaiting collection. Embodiments of the invention--sold under a variety of names, including Giant Stuff-A-Pumpkin(trade mark), Funkins, Jack Sak(trade mark), and Bag-O-Fun(trade mark)--have undisputedly been well-received by consumers, who bought more than seven million units in 1990 alone. Indeed, in 1990, the popularity of the pumpkin bags engendered a rash of thefts around Houston, Texas, leading some owners to resort to preventative measures, such as greasing the bags with petroleum jelly and tying them to trees. See R. Piller, "Halloween Hopes Die on the Vine," *Hous. Chron.*, Oct. 19, 1990, at 13A.

The road to profits has proved much easier than the path to patentability, however. In July 1989, Dembiczak filed a utility patent application generally directed to the pumpkin bags. In a February 1992 appeal, the Board of Patent Appeals and Interferences ("the Board") reversed the Examiner's rejection, but entered new grounds for rejection. Dembiczak elected to continue prosecution, filing a continuation application to address the new grounds for rejection. Thereafter, the invention made a second appearance before the Board, in April 1993, when the Board both sustained the Examiner's rejection and again entered new grounds for rejection. Again, a continuation application was filed (the instant application). And again the Examiner's rejection was appealed to the Board, which sustained the rejection in a May 14, 1998, decision. See *Dembiczak*, slip op. at 43.

A

The patent application at issue includes claims directed to various embodiments of the pumpkin bag. Claims 37, 49, 51, 52, 58 through 64, 66 through 69, and 72 through 81 are at issue in this appeal. Though the claims vary, independent claim 74 is perhaps most representative:

74. A decorative bag for use by a user with trash filling material, the bag simulating the general outer appearance of an outer surface of a pumpkin having facial indicia thereon, comprising: a flexible waterproof plastic trash or leaf bag having

an outer surface which is premanufactured orange in color for the user to simulate the general appearance of the outer skin of a pumpkin, and having

facial indicia including at least two of an eye, a nose and a mouth on the orange color outer surface for forming a face pattern on said orange color outer surface to simulate the general outer appearance of a decorative pumpkin with a face thereon,

said trash or leaf bag having first and second opposite ends, at least said second end having an opening extending substantially across the full width of said trash or leaf bag for receiving the trash filling material,

wherein when said trash or leaf bag is filled with trash filling material and closed, said trash or leaf bag takes the form and general appearance of a pumpkin with a face thereon.

All of the independent claims on appeal, namely 37, 52, 72, and 74, contain limitations that the bag must be "premanufactured orange in color," have "facial indicia," have openings suitable for filling with trash material, and that when filled, the bag must have a generally rounded appearance, like a pumpkin. Independent claims 37, 52, and 72 add the limitation that the bag's

height must at least 36 inches. Claim 72 requires that the bag be made of a "weatherproof material," and claim 74, as shown above, requires that the bag be "waterproof." Claim 52 recites a "method of assembling" a bag with the general characteristics of apparatus claim 37.

B

The prior art cited by the Board includes:

- (1) pages 24-25 of a book entitled "A Handbook for Teachers of Elementary Art," by Holiday Art Activities ("Holiday"), describing how to teach children to make a "Crepe Paper Jack-O-Lantern" out of a strip of orange crepe paper, construction paper cut-outs in the shape of facial features, and "wadded newspapers" as filling;
- (2) page 73 of a book entitled "The Everything Book for Teachers of Young Children,"

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by Martha Shapiro and Valerie Indenbaum ("Shapiro"), describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint;

(3) U.S. Patent No. 3,349,991 to Leonard Kessler, entitled "Flexible Container" ("Kessler"), describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material;

(4) U.S. Patent No. Des. 310,023, issued August 21, 1990 to Dembiczak ("Dembiczak '023"), a design patent depicting a bag with a jack-o'-lantern face;

(5) U.S. Patent No. Des. 317,254, issued June 4, 1991 to Dembiczak ("Dembiczak '254"), a design patent depicting a bag with a jack-o'-lantern face; and,

(6) Prior art "conventional" plastic lawn or trash bags ("the conventional trash bags").

Using this art, the Board affirmed the Examiner's final rejection of all the independent claims (37, 52, 72, 74) under 35 U.S.C. Section 103, holding that they would have been obvious in light of the conventional trash bags in view of the Holiday and Shapiro references. The Board determined that, in its view of the prior art, "the only difference between the invention presently defined in the independent claims on appeal and the orange plastic trash bags of the prior art and the use of such bags resides in the application of the facial indicia to the outer surface of the bag." *Dembiczak*, slip op. at 18. The Board further held that the missing facial indicia elements were provided by the Holiday and Shapiro references' description of painting jack-o'-lantern faces on paper bags. *See id.* at 18-19. Dependent claims 49 and 79, which include a "gussets" limitation, were considered obvious under similar reasoning, except that the references cited against them included Kessler. *See id.* at 7.

The Board also affirmed the Examiner's obviousness-type double patenting rejection of all the independent claims in light of the two Dembiczak design patents ('023 and '254) and Holiday. *See id.* at 12. The Board held that the design patents depict a generally rounded bag with jack-o'-lantern facial indicia, and that the Holiday reference supplies the missing limitations, such as the "thin, flexible material" of manufacture, the orange color, the initially-open upper end, and the trash filling material. The Board also stated that the various limitations of the dependent claims-- e.g., color, the inclusion of leaves as stuffing, and the dimensions--would all be obvious variations of the depictions in the Dembiczak design patents. *See id.* at 8-9. In addition, using a two-way test for obviousness-type double patenting, the Board held that the claims of the Dembiczak design patents "do not exclude" the additional structural limitations of the pending utility claims, and thus the design patents were merely obvious variations of the subject matter disclosed in the utility claims. *See id.* at 11. The Board further upheld, on

similar grounds and with the inclusion of the Kessler reference, the obviousness-type double patenting rejection of dependent claim 49. *See id.* at 12.

This appeal followed, vesting this court with jurisdiction pursuant to 28 U.S.C. Section 1295(a)(4)(A) (1994).

II

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. Section 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). We therefore review the ultimate determination of obviousness without deference to the Board, while examining any factual findings for clear error. *See, e.g., In re Zurko*, 142 F.3d 1447, 1459, 46 USPQ2d 1691, 1700 (Fed. Cir.) (en banc), *cert. granted*, 119 S. Ct. 401 (1998).

A

Our analysis begins in the text of section 103 quoted above, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the "tempting but forbidden zone of hindsight," *see Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873, 228 USPQ 90, 98 (Fed. Cir. 1985), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 USPQ2d 1097 (Fed. Cir. 1998),

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when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983). Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *Id.* Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the

combination]"); *In re Fine* , 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.* , 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham* , 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See , e.g. , *Interconnect Planning Corp. v. Feil* , 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board fell into the hindsight trap. We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.* , 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), *Para-Ordinance Mfg. v. SGS Imports Intern., Inc.* , 73 F.3d 1085, 1088, 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," *Rouffet* , 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See , e.g. , *C.R. Bard* , 157 F.3d at 1352, 48 USPQ2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." E.g. , *McElmurry v. Arkansas Power & Light Co.* , 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact."); *In re Sichert* , 566 F.2d 1154, 1164, 196 USPQ 209, 217 (CCPA 1977) ("The examiner's conclusory statement that the specification does not teach the best mode of using the invention is unaccompanied by evidence or reasoning and is entirely inadequate to support the rejection."). In addition to demonstrating the propriety of an obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the factual disputes, if any, between the applicant and the Board; and (3) facilitation of review on appeal. Here, however, the Board did not make particular findings regarding the locus of the suggestion, teaching, or motivation to combine the prior art references.

[1] All the obviousness rejections affirmed by the Board resulted from a combination of prior art references, e.g. , the conventional trash or yard bags, and the Holiday and Shapiro publications teaching the construction of decorated paper bags. See *Dembiczak* , slip op. at 6-7. To justify this combination, the Board simply stated that "the Holiday and Shapiro references would have

suggested the application of . . . facial indicia to the prior art plastic trash bags." *Id.* at 18-19. However, rather than pointing to specific information in Holiday or Shapiro that suggest the combination with the conventional bags, the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other--in combination with each other and the conventional trash bags--described all of the limitations of the pending claims. See *id.* at 18-28. Nowhere does the Board particularly

identify any suggestion, teaching, or motivation to combine the children's art references (Holiday and Shapiro) with the conventional trash or lawn bag references, nor does the Board make specific--or even inferential--findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness analysis. See, e.g., *Pro-Mold & Tool*, 75 F.3d at 1573, 37 USPQ2d at 1630.

To the contrary, the obviousness analysis in the Board's decision is limited to a discussion of the ways that the multiple prior art references can be combined to read on the claimed invention. For example, the Board finds that the Holiday bag reference depicts a "premanufactured orange" bag material, see *Dembiczak*, slip op. at 21, finds that Shapiro teaches the use of paper bags in various sizes, including "large", see *id.* at 22-23, and concludes that the substitution of orange plastic for the crepe paper of Holiday and the paper bags of Shapiro would be an obvious design choice, see *id.* at 24. Yet this reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the Holiday and Shapiro references teach or suggest their combination with the conventional trash or lawn bags to yield the claimed invention. See *Rouffet*, 149 F.3d at 1357, 47 USPQ2d at 1459 (noting Board's failure to explain, when analyzing the prior art, "what specific understanding or technical principle . . . would have suggested the combination"). Because we do not discern any finding by the Board that there was a suggestion, teaching, or motivation to combine the prior art references cited against the pending claims, the Board's conclusion of obviousness, as a matter of law, cannot stand. See *C.R. Bard*, 157 F.3d at 1352, 48 USPQ2d at 1232; *Rouffet*, 149 F.3d at 1359, 47 USPQ2d at 1459; *Fritch*, 972 F.2d at 1265, 23 USPQ2d at 1783; *Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600; *Ashland Oil*, 776 F.2d at 297, 227 USPQ at 667.

B

The Commissioner of Patents and Trademarks ("Commissioner") attempts to justify the Board's decision on grounds different from that relied upon by the Board, arguing that one of ordinary skill in the art would have been motivated to combine the references. Of course, in order to do so, the Commissioner must do what the Board did not do below: make specific findings of fact regarding the level of skill in the art ("a designer and manufacturer of trash and leaf bags, particularly one specializing in the ornamental and graphic design of such bags"), *Resp't Br.* at 14, the relationship between the fields of conventional trash bags and children's crafts, respectively ("[t]he artisan would also have been well aware of the ancillary, corollary, and atypical uses of 'trash' bags such as their application in hobby and art projects"), *Resp't Br.* at 15, and the particular features of the prior art references that would motivate one of ordinary skill in a particular art to select elements disclosed in references from a wholly different field ("a designer and manufacturer of trash and leaf bags would have recognized the paper bag in Shapiro to be a trash bag and therefore would have been motivated to combine it with the admitted prior art plastic trash and leaf bags to arrive at the claimed invention"), *Resp't Br.* at 15. The Commissioner also appears to cite additional references in support of his obviousness analysis, noting that at least two design patents (in the record but not cited against the presently pending claims) teach the placement of "graphical information, including text, designs, and even facial indicia, to colored bags." *Resp't Br.* at 16. This new analysis, apparently cut from whole cloth in view of appeal, does little more than highlight the shortcomings of the decision below, and we decline to consider it. See, e.g., *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999) ("We decline to consider [the Commissioner's] newly-minted theory as an alternative ground for upholding the agency's decision."); *In re Soni*, 54 F.3d 746, 751, 34 USPQ2d 1684, 1688 (Fed. Cir. 1995); *In re Hounsfield*, 699 F.2d 1320, 1324, 216 USPQ

1045, 1049 (Fed. Cir. 1983) (rejecting an "attempt [] by the Commissioner 'to apply a new rationale to support the rejection.'"); *see also* 35 U.S.C. Section 144 (1994) (an appeal to the Federal Circuit "is taken on the record before The Patent and Trademark Office"). Because the Board has not established a *prima facie* case of obviousness, *see In re Bell*, 991 F.2d 781,

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783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) ("The PTO bears the burden of establishing a case of *prima facie* obviousness."), we therefore reverse the obviousness rejections, and have no need to address the parties' arguments with respect to secondary factors.

III

Dembiczak also asks this court to reverse the Board's rejection of the pending claims for obviousness-type double patenting, which is a judicially-created doctrine that seeks to prevent the applicant from expanding the grant of the patent right beyond the limits prescribed in Title 35. *See, e.g., In re Braat*, 937 F.2d 589, 592, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985). *See also* 35 U.S.C. Section 154(a)(2) (Supp. 1998) (discussing patent term). The doctrine prohibits claims in a second patent which define "merely an obvious variation" of an invention claimed by the same inventor in an earlier patent. *Braat*, 937 F.2d at 592, 19 USPQ2d at 1292 (quoting *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970)). Thus, unless a claim sought in the later patent is patentably distinct from the claims in an earlier patent, the claim must be rejected. *See In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993); *Vogel*, 422 F.2d at 441, 164 USPQ at 622. This question is one of law, which we review *de novo*. *See Goodman*, 11 F.3d at 1052, 29 USPQ2d at 2015; *Texas Instruments Inc. v. United States Int'l Trade Comm'n*, 988 F.2d 1165, 1179, 26 USPQ2d 1018, 1029 (Fed. Cir. 1993).

A

[2] The law provides that, in some very rare cases, obvious-type double patenting may be found between design and utility patents. *See Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 939-40, 220 USPQ 481, 487 (Fed. Cir. 1983) (noting that, while theoretically possible, "[d]ouble patenting is rare in the context of utility versus design patents"); *In re Thorington*, 418 F.2d 528, 536-37, 163 USPQ 644, 650 (CCPA 1969) (Double patenting between a design and utility patent is possible "if the features producing the novel aesthetic effect of a design patent or application are the same as those recited in the claims of a utility patent or application as producing a novel structure."); *In re Phelan*, 205 F.2d 183, 98 USPQ 156 (CCPA 1953); *In re Barber*, 81 F.2d 231, 28 USPQ 187 (CCPA 1936); *In re Hargraves*, 53 F.2d 900, 11 USPQ 240 (CCPA 1931). In these cases, a "two-way" test is applicable. *See Carman*, 724 F.2d at 940, 220 USPQ at 487. Under this test, the obviousness-type double patenting rejection is appropriate only if the claims of the two patents cross-read, meaning that "the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the other patent, and vice versa." *Id.*, 220 USPQ at 487. *See also Braat*, 937 F.2d at 593, 19 USPQ2d at 1292 (explaining two-way test).

B

In making its double patenting rejection, the Board concluded that all but one of the pending

claims of Dembiczak's utility application would have been merely an obvious variation of the claims of the earlier-issued design patents--the Dembiczak '023 and '254 references--in light of the Holiday reference. The remaining claim, dependent claim 49, was judged obvious in light of the combination of the Dembiczak design patents, Holiday, and the Kessler reference.

[3] Acknowledging that the two-way test was required by *Carman*, 724 F.2d at 940, 220 USPQ at 487, the Board concluded that "the design claimed in each of appellants' design patents does not exclude the features pertaining to the construction and color of the bag, the use of a plastic material for making the bag, the size or thickness of the bag . . . or the use of various types of filling material The particular details of the facial indicia would have been a matter of design choice as evidenced by the Holiday handbook," and that therefore, in view of Holiday, the claims of the design patents were obvious variants of the pending utility patent claims. See *Dembiczak*, slip op. at 11. We disagree. In order for a design to be unpatentable because of obviousness, there must first be a basic design reference in the prior art, the design characteristics of which are "basically the same as the claimed design." *In re Borden*, 90 F.3d 1570, 1574, 39 USPQ2d 1524, 1526 (Fed. Cir. 1996); *In re Rosen*, 673 F.2d 388, 391, 213 USPQ 347, 350 (CCPA 1982). The phrase "having facial indicia thereon" found in the claims of the pending utility application is not a design reference that is "basically the same as the claimed design." *Borden*, 90 F.3d at 1574, 39 USPQ2d at 1526. In fact, it describes precious little with respect to design characteristics.

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The Board's suggestion that the design details were simply "a matter of design choice" evinces a misapprehension of the subject matter of design patents. *E.g.*, *Carman*, 724 F.2d at 939 n.13, 220 USPQ at 486 n.13 ("Utility patents afford protection for the mechanical structure and function of an invention whereas design patent protection concerns the ornamental or aesthetic features of a design.") Indeed, we note that the two design patents at issue here--the Dembiczak '023 and '254 patents--were considered nonobvious over each other, and were even the subject of a restriction requirement. See 35 U.S.C. Section 121 (1994) ("If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions."); 37 C.F.R. Section 1.142. The position adopted by the Board--that a textual description of facial indicia found in the claims of the utility patent application makes obvious the specific designs claimed in the (patentably distinct) Dembiczak design patents--would presumably render obvious, or even anticipate, all design patents where a face was depicted on a bag. But this, of course, is not the law; the textual description cannot be said to be a reference "basically the same as the claimed design," of the design patents at issue here. *Borden*, 90 F.3d at 1574, 39 USPQ2d at 1526 (internal quotation marks omitted). The Board's conclusion of obviousness is incorrect.

Because we find that the Board erred in concluding that the design patents were obvious variants of the pending utility claims, we need not address the other prong of the two-way double patenting test--whether the pending utility claims are obvious variations of the subject matter claimed in the design patents. See *Carman*, 724 F.2d at 939, 220 USPQ at 487 (both prongs of the two-way test required for obviousness-type double patenting). The double patenting rejections are reversed.

IV

Because there is no evidence in the record of a suggestion, teaching, or motivation to combine the prior art references asserted against the pending claims, the obviousness rejections are

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reversed. In addition, because the Board misapprehended the test for obviousness-type double patenting, and because the pending utility claims do not render obvious the design patents, the double patenting rejections are also reversed.

REVERSED .

- End of Case -

C.R. Bard Inc. v. M3 Systems Inc. (CA FC) 48 USPQ2d 1225

C.R. Bard Inc. v. M3 Systems Inc. ☐

U.S. Court of Appeals Federal Circuit
48 USPQ2d 1225

Decided September 30, 1998
No. 96-1165

Headnotes

PATENTS

1. Patentability/Validity -- Anticipation -- Identity of elements (§ 115.0704)

Verdict that patent claims for biopsy needles are invalid for anticipation is unsupported by substantial evidence, since claimed needles differ from prior art needles in flange structure for coupling needles to biopsy "gun" for movement both toward and away from housing, which is structure that limits all claims, as well as in additional limitation in two claims requiring slit in stylet head flange.

2. Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Verdict that invention of patent for biopsy needles was obvious in view of prior art is unsupported by evidence, since no prior art provided suggestion or motivation to make needle assembly with structure shown and claimed in patent, and since absent this essential evidentiary component of obviousness holding, verdict of invalidity on that ground cannot stand as matter of law.

3. Practice and procedure in Patent and Trademark Office -- Certificate of correction -- Correction of named inventor (§ 110.1205)

**Practice and procedure in Patent and Trademark Office -- Reissue -- In general
(§ 110.1301)**

Evidence does not support verdict holding patent invalid on ground that correction of inventorship was improperly made by reissue, since prosecution history shows that error in inventorship was described in reissue application and corrected by appropriate petition, filed and processed while reissue application was pending, since petition to correct inventorship may be filed during reissue proceedings, and since error in inventorship was corrected before reissue patent was granted.

**4. Practice and procedure in Patent and Trademark Office -- Reissue -- In general
(§ 110.1301)**

Primary purpose of reissue statute is to enable addition of claims to subject matter not claimed in original patent, and inventor's failure to appreciate scope of invention at time of original patent grant, and thus initial intent not to claim omitted subject matter, is remediable error.

5. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Claims for biopsy gun requiring "sequential energizing" of biopsy needles cannot be held invalid on ground that written description does not describe how to obtain elimination of all overlap of needle movement, since claims must be construed in accordance with rest of specification, not contrary to it, since specification illustrates sequential energizing of needles as having some overlap in movement, since no usage or exemplification of sequential movement in patent requires elimination of all overlap, and since correct interpretation of claims thus allows for slight overlap in needle movement; it is incorrect to construe claims in manner contrary to specification and then hold claims invalid because they are unsupported by written description.

6. Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Invention of patent for biopsy gun providing mechanical "sequential energizing" or cocking of its two biopsy needles was not obvious over combination of plaintiff's prior biopsy guns, which allowed for sequential manual cocking and mechanical, simultaneous cocking respectively, since no cited reference suggests structure employed in gun of patent, or mechanical sequential energizing, or other features of claimed gun.

7. Infringement -- Literal infringement (§ 120.05)

Patent construction -- Claims -- Means (§ 125.1307)

Means plus function claims of patent for biopsy gun providing mechanical "sequential energizing" or cocking of its two biopsy needles are not infringed by accused devices, even though accused guns also perform function of sequential energizing, since claimed structure employing rotational tensioning as energizing means is substantially different from energizing

structure in accused gun; existence of other claims in patent which specifically state structure does not warrant finding that "means" claims at issue are not limited to structure in specification, since means-plus-function limitation is not made open-ended by presence of other claims specifically claiming disclosed structure which underlies means clause or equivalent of that structure.

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8. Practice and procedure in Patent and Trademark Office -- Prosecution -- Duty of candor -- Materiality (§ 110.0903.04)

There is no presumption that information not filed by patent applicant was material simply because patentability ensued, since, to establish culpability for fraud in procurement of patent, any omission must be of fact material to patentability, and it must be deliberate misrepresentation, whether by omission or misstatement, that was intended to and did mislead examiner into taking favorable action that would not otherwise have been taken; intent to deceive or mislead must be established by clear and convincing evidence, and deceptive intent is not inferred simply because information was in existence that was not presented to examiner.

9. Patent misuse -- Federal antitrust issues (§ 140.07)

There is no presumption that patent-based right to exclude necessarily establishes market power in antitrust terms, since virtually unlimited variety and scope of patented inventions and market situations militate against per se rules; unless patent had been obtained by fraud such that market position had been gained illegally, patent right to exclude does not constitute monopoly power prohibited by Sherman Act.

10. Patent misuse -- Improper procurement and enforcement (§ 140.03)

Patent misuse -- Federal antitrust issues (§ 140.07)

Judgment finding antitrust violation cannot be sustained on ground that patentee used fraudulently obtained patent to restrain competition, since establishing liability on such ground requires showing that patent was fraudulently procured, that patentee's related commercial activity was coupled with violations of Sherman Act's Section 2, and that patentee had specific intent to monopolize, engaged in anti-competitive conduct, and had dangerous probability of success, and since, in view of incorrect verdicts of fraud in procurement of patents in suit, judgment cannot be sustained as matter of law.

11. Patent misuse -- Improper procurement and enforcement (§ 140.03)

Patent misuse -- Federal antitrust issues (§ 140.07)

Law recognizes presumption, overcome only by affirmative evidence of bad faith, that assertion of duly granted patent is made in good faith, since, absent showing that lawsuit is objectively meritless, and that suit conceals attempt to interfere directly with competitor's business relationships, patentee must have right to enforcement of duly granted patent, unencumbered by punitive consequences should patent's validity or infringement not survive litigation; judgment finding antitrust violation in present case cannot be upheld on "sham" litigation grounds, since infringement defendant failed to present substantial evidence that litigation was objectively meritless and brought in bad faith.

12. Patent misuse -- Improper procurement and enforcement (§ 140.03)

Judgment on verdicts finding patent misuse must be reversed, since there was no evidence that infringement plaintiff's competitive activities were either per se patent misuse or that they were not "reasonably within the patent grant," since conduct to which jury instruction on misuse generally referred, namely attempt to enforce patents against goods known not to be infringing, is not subject to collateral attack as new ground of "misuse," in that it is not patent misuse to bring suit to enforce patent rights not fraudulently obtained, and since verdicts thus are not supported by evidence or correct legal theory.

13. Patent misuse -- Federal antitrust issues (§ 140.07)

Judgment on jury verdict finding antitrust violation based on patentee's modification of biopsy gun to prevent use of competing replacement needles is affirmed, since evidence was sufficient to support jury's specific finding that patentee enjoyed monopoly power in market for replacement needles, and its conclusion that patentee maintained its monopoly position by exclusionary conduct; although patentee contended at trial that it modified gun in order to make it easier to load and unload, there was substantial evidence that patentee's real reasons for modification were to raise cost of entry to potential replacement needle makers, to make doctors apprehensive about using competitors' needles, and to preclude use of "copycat" needles.

Particular patents -- General and mechanical -- Biopsy guns

4,944,308, Akerfeldt, tissue sampling device, judgment of invalidity reversed; judgment of non-infringement affirmed.

Re. 34,056 (of 4,699,154), Lindgren and Akerfeldt, tissue sampling device, judgment of invalidity affirmed; judgment of non-infringement vacated.

Case History and Disposition:

Appeal from the U.S. District Court for the Northern District of Illinois, Bucklo, J.

Action by C.R. Bard Inc. against M3 Systems Inc. for patent infringement, in which defendant asserted claims for fraud, violation of antitrust laws, and patent misuse. From judgment for defendant on all issues, plaintiff appeals. Affirmed in part, reversed in part, vacated in part, and remanded.

Opinion for the court by Judge Newman except for Part I.E (on-sale issue) and Part VI.C (attempt to monopolize). Judge Bryson does not join Parts I.A-D of Judge Newman's opinion. The district court's judgment concerning the on-sale bar is affirmed in separate opinions by Chief Judge Mayer and Judge Bryson. The district court's judgment concerning the attempt to monopolize issue is reversed in part by Judge Newman's opinion (Parts VI.A-B), which Chief Judge Mayer and Judge Bryson join, and affirmed in part by Judge Bryson's opinion (Part II), which Chief Judge Mayer joins. Judge Newman dissents with respect to the on-sale bar and attempt to monopolize issues.

Related decisions: 34 USPQ2d 1474 ; 32 USPQ2d 1535 .

Attorneys:

John F. Sweeney, Harry C. Marcus, Desiree M. Stahl, Walter G. Hanchuk, Warren H. Rotert, and Steven F. Meyer, of Morgan & Finnegan, New York, N.Y., for plaintiff-appellant.

Richard D. Harris, Max Shafital, Jordan A. Sigale, and Jovan N. Jovanovic, of Dick & Harris, Chicago, Ill.; Paul E. Slater and Greg Shinall, of Sperling, Slater & Spitz, Chicago, for defendant-appellee.

Opinion Text

Opinion By:

Before Mayer, chief judge, and Newman and Bryson, circuit judges. Newman, J.

In suit are United States Patent No. 4,944,308 issued July 31, 1990 (the '308 patent) and United States Reissue Patent No. RE 34,056 issued September 8, 1992 (the '056 patent), both entitled "Tissue Sampling Device." These patents originated with the work of Dr. Per Gunner Lindgren, a physician in Sweden, and are now owned by appellant C.R. Bard, Inc.

The patented inventions are devices for taking samples of body tissue for biopsy purposes, wherein a biopsy needle firing device or "gun" mechanically injects a biopsy needle assembly into the core body tissue. These devices are described as improving the speed, accuracy, ease, and patient comfort of tissue sampling, compared with manually inserted biopsy needles. They are said to be particularly advantageous for sampling small or movable lesions and fibrous or firm tissues, because the rapidly and firmly fired needles can penetrate even fibrotic lesions before the lesions can slip aside. The patented guns and needles have achieved commercial success.

Bard sued M3 Systems in August 1993 in the United States District Court for the Northern District of Illinois, 1 asserting that M3's ProMag biopsy gun and ACN/SACN biopsy needle assemblies infringed the '308 and '056 patents, respectively. M3 raised the defenses that the patents are invalid on several grounds and are not infringed, and also charged Bard with fraud, antitrust law violation, and patent misuse. The jury rendered special verdicts in favor of M3 on every issue, finding the '056 patent invalid and not infringed on each of the grounds of anticipation, obviousness, violation of a section 102(b) bar, incorrect naming of inventors, and non-compliance with reissue requirements; and finding the '308 patent invalid and not infringed on grounds of anticipation, obviousness, and insufficient written description. The jury also found that Bard perpetrated fraud in the Patent and Trademark Office (PTO) in obtaining both patents, that Bard misused both patents, and that Bard violated antitrust law, awarding \$1.5 million in antitrust damages, trebled by the district court.

The district court denied all post-trial motions. This appeal followed. This court affirms the judgment of invalidity of the '056 patent and vacates the judgment of noninfringement of the '056 patent. The judgment of invalidity of the '308 patent is reversed and the judgment of noninfringement is affirmed. The judgments of misuse and fraud are reversed. The judgment of antitrust violation on the ground of attempt to monopolize is affirmed, but the antitrust damages award is vacated, for redetermination upon remand.

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THE PATENTED INVENTIONS

The First Generation Device -- The PCT Patent Application

In 1981 Dr. Lindgren, working in Sweden with Jan Allard, an engineer, designed and constructed the first of several successively improved mechanical biopsy guns. This "first generation" gun was designed to fire a commercially available biopsy needle assembly made by the Baxter Travenol Company, having the brand name "Tru-Cut." The Tru-Cut is a double needle consisting of a hollow outer needle called the cannula and an inner needle called the stylet. The stylet is solid except for a recess near its point. In the manual procedure for which the Tru-Cut was designed, the physician would first extend the stylet and insert the assembly into the body tissue, whereupon the tissue to be sampled would flow into the recess in the stylet; the physician would then push the cannula into the body tissue to surround the stylet and cut and trap the tissue sample in the recess.

This procedure required the physician to use both hands to manipulate the needles, while a second physician would hold and manipulate the ultrasound equipment that is usually required to view the interior of the body and direct insertion of the needles. Dr. Lindgren sought to mechanize this procedure in order to improve the speed and accuracy of insertion, to reduce human error, and to permit a physician to perform the biopsy without assistance by providing a sampling device that can be operated with one hand while the other hand holds the ultrasound apparatus.

The first generation gun is a box-like structure fitted with two spring-loaded drivers associated with slots that are configured to hold the cannula and stylet of the Tru-Cut needle assembly. To use this gun the physician must first "cock" each of the spring-loaded drivers. This cocking action, as it was often called at trial, is referred to as pre-tensioning or energizing in the patent documents. Cocking is performed by hand or with a specially designed tool described as a miniature crowbar. After the drivers are cocked, the stylet and cannula are placed in the

appropriate slots and the gun housing is closed. The gun is then aimed at the target tissue and a trigger mechanism releases the stylet and cannula in rapid sequence. The needles are then manually retrieved.

Dr. Lindgren and Mr. Allard filed a patent application on the first generation gun under the Patent Cooperation Treaty (PCT). The invention was assigned to Radiplast AB, a small Swedish company associated with Dr. Lindgren. The PCT application was filed on March 31, 1982 and was published on October 13, 1983. It is prior art to the United States patents in suit.

The Second Generation -- The '056 Reissue Patent

Starting in 1984, Dr. Lindgren undertook to improve the gun so that it would not be necessary for the physician to cock the two drivers manually before installing the biopsy needles, a step described as awkward and inefficient. In 1985 Dr. Lindgren, working with Dan degrees Akerfeldt, an engineer, designed a mechanism whereby the drivers are cocked by external action after the needles are placed in the gun and the housing is closed. In this mechanism rods are attached to each of the spring-loaded drivers, extend out the back of the gun, and culminate in a ring or handle. By pulling the ring or handle the operator simultaneously cocks both drivers, moving the needles rearward. A trigger mechanism then fires the stylet and cannula, in rapid sequence, into the tissue to be sampled.

The Tru-Cut needles were not usable with the second generation gun, for their structure was such that they could not be moved rearward as well as propelled forward. New needles were designed with a modified hub and flange structure and a slit in the stylet flange to facilitate placement in the gun. Corresponding structural changes were made to the gun to accommodate the changes in the needles. Radiplast, as assignee, filed a patent application in Sweden on February 19, 1986. The United States application was filed on July 30, 1986, naming Dr. Lindgren as the inventor. Corresponding United States Patent No. 4,699,154 (the '154 patent) was issued on October 13, 1987, with claims to the combination of the second generation gun and the new needle assembly. The '154 patent did not claim the needle assembly alone.

In 1989 Bard, having become Radiplast's distributor in 1987, acquired ownership of the Radiplast patents. Bard applied for reissue of the '154 patent in order to add claims to the needle assembly alone. This reissue patent issued on September 8, 1992, and is the '056 patent in suit. During the reissue proceeding Bard and Dr. Lindgren petitioned the PTO to correct the inventorship to include Dan degrees Akerfeldt. In addition, Bard described to the PTO various activities of Radiplast in the United States, as shall be discussed in connection with the on-sale issue.

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The Third Generation Gun -- The '308 Patent

Dan degrees Akerfeldt continued to work on improving these devices. He sought to make the gun easier to use, especially by inexperienced physicians. Because pulling the cocking ring required significant manual force to overcome the simultaneous resistance of both driver springs, he designed an external integrated cocking mechanism that energized the two springs sequentially, thereby requiring less force than did the simultaneous cocking mechanism of the second generation gun. The third generation gun also provided for separate rearward movement of the needles after the biopsy sample was taken, thereby facilitating removal of the tissue from the stylet. Radiplast applied for a United States patent on the third generation gun on November 14, 1988, naming Dan degrees Akerfeldt as inventor. The patent issued in 1990 and is the '308 patent in suit.

VALIDITY OF THE '056 REISSUE PATENT

Bard charged M3 Systems with infringement of claims 9-12 and 21-23 of the '056 patent. M3 had the burden of establishing invalidity by clear and convincing evidence at trial. *Carella v. Starlight Archery*, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir. 1986). On review, the appellate court must "decide for ourselves whether reasonable jurors viewing the evidence as a whole could have found the facts needed to support the verdict in light of the applicable law." *Lemelson v. General Mills, Inc.*, 968 F.2d 1202, 1207, 23 USPQ2d 1284, 1288 (Fed. Cir. 1992). The appellant must establish that the jury's actual or inferred factual findings were not supported by substantial evidence, or that the found or inferred facts were not sufficient to support the conclusion, or that the law was incorrectly applied. See, e.g., *Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1376, 47 USPQ2d 1289, 1290 (Fed. Cir. 1998); *D.M.I., Inc. v. Deere & Co.*, 802 F.2d 421, 425, 231 USPQ2d 276, 278 (Fed. Cir. 1986).

When a claim or defense can not be maintained or defeated without a favorable finding on a material issue, and there is not substantial evidence supporting that finding, the verdict can not stand and the court must render judgment as a matter of law. See Fed. R. Civ. P. 50; *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986); see generally *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975, 34 USPQ2d 1321, 1326 (Fed. Cir. 1995) (in banc), *aff'd*, 517 U.S. 370, 38 USPQ2d 1461 (1996). The appellate court must determine whether on the evidence of record a jury might properly have returned a verdict in the non-movant's favor when the correct legal standard is applied. If not, the movant was entitled to have the question removed from the jury and decided as a matter of law.

We apply these principles to each of the grounds on which the jury rendered verdicts of invalidity of the asserted '056 claims. We direct our discussion of validity primarily to claim 21, for the claim is representative and M3 Systems' expert witnesses admitted infringement of claim 21 by M3's original ACN needles:

21. A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:
a hollow first needle having proximal and distal ends;
a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;
a first head mounted to said proximal end of said hollow first needle, said first head including first flange means associated therewith for coupling said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end of said housing; and
a second head mounted to said proximal end of said second needle, said second head including second flange means associated therewith for coupling said second needle to said second slide for longitudinal motion both toward and away from said forward end of said housing.

A. Anticipation

To meet the requirements of patentability a device must be new; that is, it must not have been previously known. Section 102(a) requires that the subject matter was not published anywhere, or known or used by others in the United States, before its invention by the patentee. 2 An invention that

does not meet the requirements of novelty in section 102(a) is said to be "anticipated."

When the defense of lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device. *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 USPQ2d 1133, 1136 (Fed. Cir. 1992); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984). The jury found that all of the claims at issue were "fully anticipated by a single prior art reference." Bard states that no reference described the new biopsy needle assembly of the '056 patent, and that the closest prior art, which all agree is the Travenol Tru-Cut needle assembly, differs in material ways. M3 Systems states that the Tru-Cut (or a publication describing the Tru-Cut) anticipated the claimed needle assembly because the '056 claims, correctly construed, read on the Tru-Cut.

The district court declined to construe all of the claim terms that were placed in dispute, instructing the jury that "words in a claim are to be given their ordinary and accustomed meaning, unless it appears that the inventor intended to use them differently. . . . You may use the specification to interpret what the patentee meant by a word or phrase in a claim." The record shows that the court defined some terms and the parties explained their views to the jury. This procedure was not incorrect at the time this case was tried -- for as the court observed, the question of the relative roles of judge and jury was then before the Supreme Court -- and does not of itself warrant a new trial. On appellate review, however, we apply the principles of *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454-56, 46 USPQ2d 1169, 1172-75 (Fed. Cir. 1998) (in banc), and determine whether on the correct claim construction the jury verdict can stand. See *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568, 41 USPQ2d 1225, 1236 (Fed. Cir.) (reviewing whether the verdict reached was in accordance with correct claim construction), *cert. denied*, 118 S. Ct. 369 (1997).

1. The Term "Freely Slidable"

M3 Systems contends that the claim term "freely slidable" does not distinguish the '056 claims from the Tru-Cut needle assembly. The term "freely slidable" appears in the following claim clause:

a second needle extending through said hollow first needle and freely slidable therewithin, . . . Bard argues that the court should have construed "freely slidable" for the jury, and that correctly construed this term means that the needle slides freely in either direction. M3 responds that Bard improperly seeks to insert the limitation "totally" into the definition of "freely slidable" and that, correctly construed, "freely slidable" requires only sliding freely in the forward direction. M3 states that since the Tru-Cut is freely slidable in the forward direction, the claim reads on the prior art and is invalid for anticipation.

M3 Systems' proposed claim construction is not correct, and could not have reasonably been adopted. The specification leaves no uncertainty that the '056 needles are freely slidable in both directions, for that is a purpose of the new '056 needle structure. M3's proposed interpretation is unsupported by, and indeed is contrary to, the specification. See *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1116, 1 USPQ2d 1563, 1566 (Fed. Cir. 1987) (claims are not interpreted "in a vacuum," but are read and understood in light of the specification of which they are a part). The jury's finding of anticipation can not be sustained if grounded on M3's interpretation of "freely slidable," for it was not disputed that the prior art Tru-Cut needles can not slide in both directions.

2. The "Housing"

M3 Systems argues that the preamble of the '056 claims refers only to the "housing" of the

tissue sampling device, and that the lack of any preamble reference to an external automatic cocking mechanism invalidates the claims by anticipation because they fail to distinguish the gun of the preamble from the prior art first generation gun.

M3 Systems has incorrectly construed the claim preamble. A preamble may serve a variety of purposes, depending on its content. It may limit the scope of the claim, for example when patentability depends on limitations stated in the preamble, as in *In re Stencel*, 828 F.2d 751, 754, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987), or when the preamble contributes to the definition of the claimed

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invention, as in *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). In this case, however, the preamble simply states the intended use or purpose of the invention, as in *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 868, 228 USPQ 90, 94 (Fed. Cir. 1985). Such a preamble usually does not limit the scope of the claim unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly. In *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 880, 20 USPQ2d 1045, 1053 (Fed. Cir. 1991), for example, the preamble described a "reference point" that provided guidance in understanding and construing the claim.

In the case at bar, the preamble of claim 21 recites the portion and structure of the gun housing into which the needles fit, and provides reference points in the gun that aid in defining the needles as set forth in the body of the claim. M3 Systems is incorrect in stating that the preamble must contain details of the integrated mechanical cocking structure, for the gun structure is not part of the separate claims to the needles. The question of anticipation of the '056 claims relates to the needles, not the gun. To the extent that the jury verdicts of anticipation may have been based on M3's incorrect construction of the preamble, they can not be sustained. On the correct construction of the preamble, it contributes no basis of invalidity on the ground of anticipation.

3. The On-sale Bar and "Anticipation"

M3 Systems defends these anticipation verdicts by arguing that the asserted claims are anticipated because they are subject to an on-sale bar. Although 35 U.S.C. Section 102(b) provides that an inventor's sales or offers of sale more than one year before the patent filing date may bar the grant of a valid patent, the on-sale bar is an independent ground of invalidity based on the inventor's delay in entering into the patent system. Although the on-sale bar can arise from one's own invention, "anticipation" does not arise from sale of one's own invention. We discuss the on-sale issue *post*; however, this aspect is unrelated to the "anticipation" verdicts, was not part of the jury instruction on that issue, and is not based on correct law.

Conclusion

[1] In sum, M3 Systems directs us to no prior art or prior knowledge or use by others that constitutes substantial evidence of anticipation of the needles claimed in the '056 patent. M3's witnesses conceded that the '056 needles differ from the Tru-Cut in the flange structure for coupling to the gun for movement both toward and away from the housing, a structure that limits all claims, as well as in the additional limitation in claims 10 and 12 of a slit in the stylet head flange. It is not disputed that the Tru-Cut needle assembly lacks these elements. In view of these admitted differences between the '056 needles and the prior art, differences unambiguously stated in the '056 claims, the verdicts of anticipation are unsupported by substantial evidence. The judgment of invalidity on this ground is reversed.

B. Obviousness

Invalidity based on obviousness is a question of law based on underlying facts. See *Graham*

v. John Deere Co. , 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966); *Panduit Corp. v. Dennison Mfg. Co.* , 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1595-97 (Fed. Cir. 1987). The relevant facts relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying. *Graham* , 383 U.S. at 17, 148 USPQ at 467; *see Continental Can Co. USA, Inc. v. Monsanto Co.* , 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750-51 (Fed. Cir. 1991).

The ultimate determination of obviousness *vel non* is a legal conclusion. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.* , 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985). When a patent describes a new mechanical device that can be viewed as a new combination or arrangement of mechanical components, the legal conclusion of obviousness requires that there be some suggestion, motivation, or teaching in the prior art whereby the person of ordinary skill would have selected the components that the inventor selected and used them to make the new device. *See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.* , 21 F.3d 1068, 1072, 20 USPQ2d 1377, 1379 (Fed. Cir.

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1993) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination."); *Northern Telecom, Inc. v. Datapoint Corp.* , 908 F.2d 931, 934, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990) (it is insufficient that prior art shows similar components, unless it also contains some teaching, suggestion, or incentive for arriving at the claimed structure). We review a jury verdict of obviousness to determine whether substantial evidence supports the factual findings predicate to the legal conclusion of obviousness and whether such findings can support the verdict, with appropriate consideration of the presumption of validity and the requirement that obviousness be proved by clear and convincing evidence; factual inferences are drawn and credibility determinations are accepted in favor of the verdict winner. *See Richardson-Vicks Inc. v. Upjohn Co.* , 122 F.3d 1476, 1480, 44 USPQ2d 1181, 1183-84 (Fed. Cir. 1997); *Structural Rubber Prod. Co. v. Park Rubber Co.* , 749 F.2d 707, 718-19, 223 USPQ 1264, 1273 (Fed. Cir. 1984).

M3 Systems argued at trial that the patented needle assembly would have been obvious in light of the Tru-Cut needle assembly, and that the only differences arose from obvious adaptations to accommodate the new gun design and to provide the desired reverse movement of the needles. No other prior art was presented. The invention that was made, however, does not make itself obvious; that suggestion or teaching must come from the prior art. *See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp.* , 837 F.2d 1044, 1051-52, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988) (it is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so); *Interconnect Planning Corp. v. Feil* , 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (it is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor); *Fromsom v. Advance Offset Plate, Inc.* , 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985) (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

[2] No prior art provided a teaching or suggestion or motivation that a needle assembly should be made with the structure shown and claimed in the '056 patent. Absent this essential evidentiary component of an obviousness holding, as a matter of law the verdicts of invalidity

on that ground can not stand. Consequently, the judgment of invalidity based on obviousness is reversed.

C. *Inventorship*

The jury rendered special verdicts of invalidity of the asserted '056 claims on the ground of incorrect inventorship. Inventorship is a question of law, applied to relevant facts. Findings of relevant fact are reviewed on the standard appropriate to the trier of fact, in this case for substantial evidence. See *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980, 41 USPQ2d 1782, 1786 (Fed. Cir.), cert. denied, 117 S. Ct. 2459 (1997). The application of law to the found or admitted facts is reviewed on appeal without deference to the trier of fact. See *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460, 45 USPQ2d 1545, 1547 (Fed. Cir. 1998); *Sewall v. Walters*, 21 F.3d 411, 415, 30 USPQ2d 1356, 1358 (Fed. Cir. 1994).

The "inventor," in patent law, is the person or persons who conceived the patented invention. *Collar Co. v. Van Dusen*, 90 U.S. (23 Wall.) 530, 563-64 (1874); *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1227-18, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994) ("Conception is the touchstone of inventorship.") Thus facts relevant to inventorship are those showing the conception of the invention, for others may provide services in perfecting the invention conceived by another without becoming an "inventor" by operation of law. *Id.*; *Agawam Co. v. Jordan*, 74 U.S. (7 Wall.) 583, 602-04 (1868); *Hess*, 106 F.3d at 980-81, 41 USPQ2d at 1786-87. As explained in *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 785 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), "an inventor may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent."

An assertion of incorrect inventorship must be based on facts proved by clear and convincing, corroborated evidence. *Hess*, 106 F.3d at 980, 41 USPQ2d at 1786. The difficulty of determining legal inventorship has been recognized, see *Jamesbury Corp. v. United States*, 518 F.2d 1384, 1396, 183 USPQ 484, 489 (Ct. Cl. 1975) (inventorship is one of the most difficult issues in American patent law) and, to avoid inadvertent invalidity, 35 U.S.C. Section 256 permits correction of the designated inventorship of a patent when an error was made without deceptive intent:

Section 256 Whenever through error a person is named in an issued patent as the inventor,

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or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

See *Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551, 1556, 43 USPQ2d 1321, 1325 (Fed. Cir. 1997) (error in inventorship may be corrected at any time if no deceptive intent).

The '154 patent as filed in the United States had named Dr. Lindgren as sole inventor. In the course of the reissue proceeding Dr. Lindgren filed a petition in the PTO to add Dan degrees Akerfeldt as a joint inventor. Lindgren and degrees Akerfeldt each filed declarations explaining their roles in the invention and declaring that the omission in naming degrees Akerfeldt was due to differences between United States and Swedish patent law, and was not done with intent to deceive.

M3 Systems challenged the joint inventorship of Lindgren and degrees Akerfeldt, and also stated that neither one was an inventor of the '056 patent's needles, but that Alan Taylor, President of Hart Enterprises, the company Radiplast retained to manufacture its new needles in

the United States, was the sole inventor. Although Mr. Taylor did not appear at the trial, he stated in a deposition that he was not an inventor, but that he suggested the slot in the stylet flange to cooperate with a guide pin in the gun and prevent rotation of the needle. He said he sketched his design for Mr. Engstrom, although such a sketch was not produced. M3 states that Mr. Taylor gave written notice of his claim in 1990, before the reissue application was filed, but the record citations in M3's brief do not direct us to such notice.

It has long been the rule that one who asserts "inventor" status must provide clear and convincing evidence of supporting facts, including corroborating evidence. *See Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371, 47 USPQ2d 1363, 1366 (Fed. Cir. 1998) (illustrating the historical distrust of uncorroborated oral testimony of prior invention and citing the "rule of reason" analysis of corroborating evidence in *Price v. Symysk*, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir. 1993)). At the trial Mr. Engstrom disputed Mr. Taylor's statements, and the earliest depiction introduced of the flange with a slot was a Swedish document.

Alternatively, M3 Systems points to the design patents that were filed in the name of degrees Akerfeldt alone, as establishing that Dr. Lindgren was not a joint inventor of the needles with degrees Akerfeldt. Bard replies, and there is no dispute, that the design patents showed specific hub designs not shown in the utility patent. Whether degrees Akerfeldt was the sole inventor of specific hub designs does not negate his joint inventorship of the needles of the '056 patent, which are depicted and claimed broadly. Bard also stresses that if indeed there were error in inventorship, such errors are correctable and do not invalidate the patent absent deceptive intent. To invalidate a patent based on incorrect inventorship it must be shown not only that the inventorship was incorrect, but that correction is unavailable under section 256:

Section 256 [Para.2] The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. . . .

Although M3 contends that deceptive intent can be inferred from the omission of Taylor as an inventor, precedent requires that one who claims a share of inventorship must establish that right by clear and convincing evidence. *Ethicon*, 135 F.3d at 1465-66, 45 USPQ2d at 1552; *Hess*, 106 F.3d at 980, 41 USPQ2d at 1785-86. Since such evidence was absent, the judgment of invalidity based on incorrect inventorship can not stand, and is reversed.

D. Violation of Reissue Requirements

The jury also found by special verdicts that the asserted '056 claims were invalid on the ground that the reissue requirements were not met. M3 Systems explains in its brief that the jury found that "any purported error in the '154 patent could *not* be corrected by reissue," explaining that the errors were the error in inventorship and the error in failing to claim the needles in the original '154 patent.

[3] With respect to the argument that the correction of inventorship was improperly made by reissue, we have been directed to no legal or procedural error, for the prosecution history clearly shows that the error in inventorship was described in the reissue application and corrected by appropriate petition, filed and processed while the reissue application was pending. A petition to correct inventorship, 37 C.F.R. Section 1.324 (1991), may be filed during reissue proceedings. The error in inventorship was corrected before the reissue patent was granted, and thus the reissued patent names Lindgren and degrees Akerfeldt as the inventors. This procedure can not have provided ground for a reasonable jury's verdicts

of invalidity based on violation of reissue requirements.

[4] The other aspect that M3 Systems argued was not amenable to correction by reissue was the addition of claims to the needles per se. That argument incorrectly states the reissue law, for a primary purpose of the reissue statute is to enable the addition of claims to subject matter not claimed in the original patent. See *Scripps Clinic & Res. Found'n v. Genentech, Inc.*, 927 F.2d 1565, 1575, 18 USPQ2d 1001, 1009 (Fed. Cir. 1991) (purpose of reissue statute is to avoid forfeiture of substantive rights due to erroneously claiming less than entitled, through error without intent to deceive); *In re Wilder*, 736 F.2d 1516, 1518-19, 222 USPQ 369, 371-72 (Fed. Cir. 1984) (purpose of reissue is to correct errors such as misunderstanding scope of the invention and claiming less than that to which the inventor was entitled).

M3 Systems states that since the needles were not claimed originally they were not "intended" to be claimed, and that absence of such intent is not an error correctable by reissue. That too is an incorrect statement of the law. An inventor's failure to appreciate the scope of an invention at the time of the original patent grant, and thus an initial intent not to claim the omitted subject matter, is a remediable error. See *In re Amos*, 953 F.2d 613, 619, 21 USPQ2d 1271, 1276 (Fed. Cir. 1991) (reissue application not subject to rejection for failure to demonstrate initial intent to claim, when subject matter of reissue claims satisfies Section 112 requirements); *In re Weiler*, 790 F.2d 1576, 1581, 229 USPQ 673, 676-77 (Fed. Cir. 1986) ("intent to claim" is shorthand for a means of measuring whether required error is present); *In re Hounsfeld*, 699 F.2d 1320, 1322, 216 USPQ 1045, 1048 (Fed. Cir. 1983) (lack of "intent to claim" is only one factor to be considered).

M3 Systems also argues that the error in failing to claim the needles should have been corrected sooner. The reissue statute sets a two-year time limit for filing a broadening reissue application. This requirement was met. See 35 U.S.C. Section 251; *In re Graff*, 111 F.3d 874, 877, 42 USPQ2d 1471, 1473-74 (Fed. Cir. 1997) (broadened claims must be filed within two years); see also 37 C.F.R. Section 1.175 (1991). There is no requirement that a patentee act earlier rather than later during the two-year window established by statute.

M3 Systems has stated no basis in fact or law for its assertion that any reissue procedure was violated. The verdicts of invalidity on this ground are unsupported in law, and judgment based thereon is reversed.

E. The On-Sale Issue 4

The jury also found that the asserted '056 claims were invalid on the ground that the new needle assembly had been "patented or published or in public use or on sale" in the United States more than one year before the filing date of the '154 patent application in the United States. See 35 U.S.C. Section 102(b), *supra* note 3. Since that filing date was July 30, 1986, the critical date for bar purposes is July 30, 1985.

Although the special verdicts did not distinguish among the statutory grounds of patented or published or in public use or on sale, the major focus at trial and on appeal is the issue of on sale. While M3 Systems also argued that there was a bar based on publication and public use, the only evidence referred to relates to the first generation gun and the Tru-Cut needles, which are acknowledged prior art and are not claimed in the patents in suit. M3's argument at trial that these prior art devices were also a bar to the '056 claims under section 102(b) is not pressed on appeal.

The '154 and '056 patents are directed to the second generation gun and new needles. Before the critical date, indeed before the development of the second generation gun and new needles had been completed, Radiplast was engaged in a variety of activities directed to the United States market. These activities included demonstrating and promoting the first generation gun with the Tru-Cut needles, pursuing arrangements for clinical trials for the second generation gun and

new needles through collaboration with a potential United States distributor, applying for FDA approval, arranging for manufacture of the needles in the United States, and related activities directed to commercial goals. Although Radiplast's final needle design was developed after the critical date, the issue at trial was the effect of these prior activities under the law of section 102(b).

Federal Circuit precedent on the on-sale bar requires consideration by the court of the totality of the circumstances in light of the various policies that underlie the bar. Precedent explains that "while a wide variety of factors may influence the on sale determination,

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no single one controls the application of section 102(b), for the ultimate conclusion depends on the totality of the circumstances." *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1514 (Fed. Cir. 1995); see *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990).

Although a few cases have recognized the advantages of a bright line rule that would be applicable in all cases, that is, a defining event whereby an inventor will know when the bar will accrue, generally the court has undertaken to weigh the particular facts of the commercial activity against the particular policy considerations that apply to the situation, giving effect to the principle that "the policies or purposes underlying the on sale bar, in effect, define it." *RCA Corp. v. Data General Corp.*, 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). Thus, in general, "this court has been careful to avoid erecting rigid standards for 102(b)." *Western Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 844, 226 USPQ 334, 337 (Fed. Cir. 1985); see *Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 1425, 40 USPQ2d 1201, 1203 (Fed. Cir. 1996) ("This court has emphasized that the totality of the circumstances must be considered in determining whether a particular event creates an on-sale or public use bar." (quoting *U.S. Environmental Prods., Inc. v. Westall*, 911 F.2d 713, 716, 15 USPQ2d 1898, 1901 (Fed. Cir. 1990))).

The determination of whether a product was on sale in terms of section 102(b) is a question of law. See *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544, 41 USPQ2d 1238, 1243-44 (Fed. Cir. 1997) (discussing precedent and applying the totality of the circumstances standard as a matter of law); *KeyStone Retaining Wall Sys., Inc. v. Westrock, Inc.*, 997 F.2d 1444, 14451, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993) (explaining relevant factual inquiries); *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1562-64, 4 USPQ2d 1210, 1213-14 (Fed. Cir. 1987) (discussing various factors to be weighed in context of experimental testing by third persons).

The various policy considerations include the policy of providing a limited but normally sufficient time (one-year) for the inventor to test the commercial reception of the invention before deciding whether it warrants patenting; the policy of limiting the period during which the patentee may delay entering into the patent system for the purpose of deferring the end of the period of patent-based exclusivity; the policy favoring prompt public disclosure of inventions through the patent system; and the policy of recognizing the practical consideration whereby the value of an invention may not be known until it is publicly tested. Depending on the dominant policy considerations in the particular case, applied to the factual circumstances of that case, the Federal Circuit has reached a variety of conclusions as to when the on-sale bar arose. The court's precedent illustrates rulings ranging from the requirement that the patented product was produced and available commercially before the on-sale bar started to accrue, to rulings that the bar was triggered before the invention had been completed.

Before the critical date for the '056 patent, July 30, 1985, three sets of events were explored at trial. The facts are not in dispute; the question is whether, as a matter of law, the on-sale bar arose in these circumstances:

1. *The Clinical Trials*

The clinical trials were arranged by American Pharmaseal, Radiplast's potential distributor in the United States, and were conducted in August and September 1985 (after the critical date) using the second generation guns and new needles. In January 1985 Thomas Engstrom of Radiplast had quoted to Pharmaseal the price for 12 guns and 500 needles for use in the trials. Pharmaseal later that spring requested 10 guns and 250 needles, for which Radiplast sent an invoice in June 1985. Mr. Engstrom testified that this payment was to defray some of Radiplast's costs in providing these devices, and was so understood. It was not disputed that the transaction produced no profit for Radiplast.

M3 Systems asserts that Radiplast sold the 10 guns and 250 needles to Pharmaseal, pointing out that a standard sales invoice was used. Bard replies that this was a transaction between collaborators, not a commercial sale and not a sale for commercial distribution. Dr. Lindgren testified that he visited the four United States hospitals that were testing the device (after the critical date), to explain its use and to see how it worked in different tissues, operated by different doctors. Bard stresses that the devices were not sold, that all but one were returned by the hospitals after the clinical trials, and unused needles were destroyed.

Generally cost defrayal arrangements between collaborators are not deemed to be invalidating sales, nor are payments for use substantially for test purposes. See *In re Mahurkar*, 71 F.3d 1573, 1577, 37 USPQ2d 1138, 1142 (Fed. Cir. 1995) (actual sale of two prototype catheters "did not place the

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invention in the public domain or lead the public to believe that the device was freely available"); *Ethicon, Inc. v. United States Surgical Corp.*, 762 F. Supp. 480, 506-07, 19 USPQ2d 1721, 1740 (D. Conn. 1991) (clinical tests by surgeon not a public use under Section 102(b)), *aff'd*, 765 F.2d 1062 (Fed. Cir. 1992) (Table); *Baker Oil Tools*, 828 F.2d at 1564, 4 USPQ2d at 1214 (discussing factors in deciding whether the purpose of testing was primarily experimental). In its submissions to the PTO during the reissue proceeding Radiplast characterized the transaction concerning the 10 guns and 250 needles as for experimental purposes.

It is not disputed that the sole purpose of this transaction was to make the devices available to the four selected hospitals for a limited test period. Radiplast's arrangement with Pharmaseal for payment or defrayal of the cost of providing the devices was not a sale or offer of sale as contemplated by section 102(b). It contravenes none of the policies underlying the on sale bar for Radiplast to have recouped these costs. Upon considering the totality of the circumstances, I conclude that an on-sale bar did not arise based on this transaction between Radiplast and Pharmaseal in connection with the clinical trials.

2. *The Bulk Price Quotation*

In January 1985 Radiplast quoted to Pharmaseal prices for various bulk quantities of up to 50,000 needles. At that time the new needles were still being modified, and the record shows that design changes were made well after January 1985. Mr. Engstrom of Radiplast testified that the quotation was information for a potential distributor, in the event that Pharmaseal accepted that role (it did not). The bulk price quotations were in a telex that stated, "This is to give you an indication of the price levels. We have to meet and discuss more in detail all things related with

the marketing of our biopsy instrument in US." It was not disputed that the quotation was for modified needles, and that both parties understood that the modified needles were not yet available.

M3 Systems argues that since the first generation device had been shown to operate for its intended purpose using Tru-Cut needles, the inventor had already convinced himself that he had a satisfactory product that he wished to commercialize in the United States, and thus that the bulk price quotation, even if for needles not yet developed, was an on-sale event. M3 stresses that the price quoted for bulk quantities included a profit for Radiplast, unlike the price for the clinical trial quantities.

Quotation of a sales price to a potential distributor of a product that is not available for sale and distribution does not of itself establish an on-sale bar. See *Continental Can*, 948 F.2d at 1270, 20 USPQ2d at 1750 (price terms set between collaborators in joint research not an on-sale bar); *Shatterproof Glass*, 758 F.2d at 622, 225 USPQ at 639 ("clear weight of authority is that a bare offer to sell does not ipso facto satisfy the 'on sale' bar"). A primary policy served by the on-sale bar is to provide time for an inventor to determine the reception of his invention in the marketplace before entering into the patent system, while the one-year limit prevents undue lengthening of the period of exclusivity. The policy is served when cognizance is taken of whether the invention is ready for commercial use at the time that customer contacts are made. Although exceptions have arisen on particular facts, normally the on-sale bar does not accrue based on customer contacts made while the product is still being developed or tested. See *KeyStone*, 997 F.2d at 1451, 27 USPQ2d at 1303 (on-sale bar "requires that the device asserted to be on sale was operable"); *Seal-Flex Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1322, 40 USPQ2d 1450, 1452 (Fed. Cir. 1996) (invention not completed if it required testing under conditions of actual use).

In this case, the circumstances of the incomplete stage of development of the second generation gun and proposed new needles at the time of this price quotation, the potential but not established distributor relationship underlying this quotation, the planned clinical collaboration, and the non-existence of a completed final product, negate the accrual of an on-sale bar from this price quotation. It seems clear that neither Radiplast nor Pharmaseal expected that this bulk price quotation would be followed by the placement of an order. To satisfy the on-sale requirement of section 102(b) there must be more than an informational exchange of price information, when there is no reasonable contemplation that the quotation will be followed by purchase and sale as a commercial transaction.

I conclude that the verdicts of invalidity based on the on-sale bar can not be supported by this bulk price quotation.

3. *The Correspondence with Dr. Phelps*

The third event raised by M3 Systems occurred in November 1984. Mr. Engstrom of Radiplast responded to a letter written in September 1984 by Dr. Phelps, a physician

in Alabama, who had seen a demonstration and brochure for the first generation device and wrote to Sweden for information. Engstrom wrote back that he hoped to start marketing a second generation device and new needles in the United States in early 1985, and that if Dr. Phelps did not wish to wait until United States distribution was arranged he could order directly from Sweden; the letter quoted prices for a gun and needles. No further correspondence ensued. Dr. Phelps testified that he expected that had he sent an order it would have been filled, and that he knew nothing about the difference between "generations." Mr. Engstrom testified that neither

the new needles nor the completed second generation gun was available when he answered Dr. Phelps.

An offer of sale originating in a foreign country, directed to a consumer in the United States, can establish an on-sale bar as to what was offered. *In re Caveney*, 761 F.2d 671, 676-77, 226 USPQ 1, 4 (Fed. Cir. 1985). The demonstration and brochure that led to Dr. Phelps' inquiry were of the first generation device, which used Tru-Cut needles. Although the details of Radiplast's product changes were not explained to Dr. Phelps it was undisputed that an order, if placed, could not have been filled at that time with the second generation gun and needles. *Cf. King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985) (finding it significant that purchaser could discern that it was the later-patented invention being offered for sale).

At the time of Mr. Engstrom's letter the second generation device and needles were in an early development stage. Although Dr. Phelps was not told the details of these developments, this correspondence did not raise an on-sale bar to a product not yet developed. As held in *Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 112 F.3d 1163, 1167-68, 42 USPQ2d 1619, 1623 (Fed. Cir. 1997), "subsequent completion of an invention after the critical date does not relate back to the date of an earlier alleged offer of sale." *See also Micro Chem.*, 103 F.3d at 1544-45, 41 USPQ2d at 1243 (no on-sale bar when invention not completed at time of offer, only prototype and sketch of proposed configuration); *Shatterproof Glass*, 758 F.2d at 622, 225 USPQ at 639 (not an on-sale bar to solicit orders before invention completed); *cf. Pfaff v. Wells Elecs., Inc.*, 124 F.3d 1429, 43 USPQ2d 1928 (Fed. Cir. 1997), *cert. granted*, 118 S. Ct. 1183 (1998) (No. 97-1130) (although invention not reduced to practice because no physical embodiment had been made, the firm purchase order and delivery date accrued the on-sale bar) (citing *UMC Elecs. Co. v. United States*, 816 F.2d 647, 2 USPQ2d 1465 (Fed. Cir. 1987)). On the totality of the circumstances, considering the relevant policies and the undisputed facts, I conclude that this letter to Dr. Phelps, written in response to an inquiry about the first generation device, which resulted from a brochure on the first generation device, stating the price for the second generation device and needles before they were fully developed and before they were available, did not trigger the on-sale bar.

Upon *de novo* review of the totality of the circumstances, with due consideration to the applicable policies, the undisputed facts, and drawing factual inferences in favor of the verdicts, I conclude that the verdicts of invalidity based on a section 102(b) bar are incorrect; I would reverse the judgment on that ground. 5

II

INFRINGEMENT OF THE '056 PATENT

In view of the majority's affirmance of the judgment of invalidity, we do not reach the issue of infringement of the '056 patent. That judgment is vacated.

III

VALIDITY OF THE '308 PATENT

The '308 patent is directed to the third generation gun. The jury found the asserted claims of the '308 patent not infringed, and invalid or unenforceable on the grounds of anticipation, obviousness, and insufficient

supporting description, as well as for fraud, misuse, and violation of antitrust law, as discussed in Parts V-VII, *post*.

Claims 15 and 16 were at issue, with emphasis added to show the claim terms whose construction is relevant to the issues of patent validity or infringement: 15. A tissue sampling device comprising:

a guide sleeve having front and rear guide sleeve ends and defining a longitudinal axis extending between said front and rear guide sleeve ends, said front guide sleeve end having an opening therethrough;
a hollow first needle positioned within said guide sleeve and extendable from said opening, said hollow first needle being moveable along said axis;
a second needle extending through said hollow first needle and moveable along said axis, said second needle having a tip which is extendable from said hollow first needle and said opening, and said second needle further including a tissue sample receiving recess;
a first needle head coupled to said hollow first needle and *mounted within said guide sleeve* for movement along said axis to move said hollow first needle along said axis;
a second needle head coupled to said second needle and *mounted within said guide sleeve* for movement along said axis to move said second needle along said axis;
a first spring *disposed within said guide sleeve* and operatively associated with said second needle head, said first spring being capable of being placed into an energized mode to store energy, and said first spring being releasable from said energized mode to propel said second needle head along said axis towards said opening, such that said tip of said second needle is extended from said hollow first needle, whereby a tissue sample can be captured within said recess;
a second spring *positioned within said guide sleeve* and operatively associated with said first needle head, said second spring being capable of being placed into an energized mode to store energy, and said second spring being releasable from said energized mode to propel said first needle head along said axis towards said opening, said hollow first needle being extended from said opening such that said recess of said second needle is enclosed by said hollow first needle;
a first latch means selectively releasable from outside said guide sleeve for releasably holding said first spring in said energized mode;
a second latch means for releasably holding said second spring in said energized mode, said second latch means being releasable in response to and subsequent to release of said first spring;
and *sequential energizing means operative to move said first needle head* along said axis towards said rear guide sleeve end to cause said second latch means to hold said second spring in said energized mode, *and subsequently to move said second needle head* along said axis towards said rear guide sleeve end to cause said first latch means to hold said first spring in said energized mode.

Claim 16 is the same as claim 15 except for the last clause, which includes the selective retraction of the stylet to expose the tissue sample:

16. . . . *energizing means operative to move said first needle head and said second needle head* along said axis towards said rear guide sleeve end to cause said first latch means to hold said first spring in said energized mode and to cause said second latch means to hold said second spring in said energized mode, said *energizing means* being selectively operative to move said first needle head but not said second needle head towards said rear guide sleeve end, whereby said hollow first needle is selectively retractable to expose said tissue sample receiving means in said second needle.

A. *Support by the Written Description*

The jury found claims 15 and 16 "not supported by the description contained in the specification." M3 Systems explains that the issue was the meaning of the claim terms "sequential energizing" and "energizing means." The district court had permitted the jury to resolve this disputed issue of claim construction. On this appeal we give *de novo* review to the issues relevant to the construction and interpretation of the claims. See *Cybor*, 138 F.3d at 1454-56, 46 USPQ2d at 1172-75.

M3 Systems states that "sequential" should be construed, and was construed by the jury, to permit no overlap of needle movement during the energizing step. M3 states that since the patent shows that the second needle can start to move before the first needle has completed its movement, the written description does not support the claims. M3 states, as it did at trial, that since the specification does not describe how to obtain elimination of all overlap of needle

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movement, the claims are not supported by the written description and are invalid.

[5] Bard agrees that the specification shows a slight overlap in the movement of the needles, whereby the second needle starts to move just before the first needle has completed its movement and the first spring latches. Thus, Bard contends, correct interpretation of the claims allows for this slight overlap in needle movement. Bard states that it is incorrect to construe the claims contrary to the specification, and then to hold the claims invalid because they are contrary to the specification. Bard is of course correct; the claims are construed in accordance with the rest of the specification of which they are a part, and not contrary to it. See *Slimfold Mfg.*, 810 F.2d at 1116, 1 USPQ2d at 1566; *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1125, 227 USPQ 577, 585 (Fed. Cir. 1985) (in banc).

The specification illustrates the sequential energizing of the needles as having some overlap in movement of the needles. The term "sequential" in the claims is in accordance with this description in the specification; no usage or exemplification of the sequential movement requires eliminating all overlap. It is incorrect to construe the claims as barring all overlap, as urged by M3 Systems. On the correct claim construction, no reasonable jury could have found that the claims are not supported by the description in the specification. It is thus apparent that the jury either adopted M3's erroneous claim construction, or incorrectly applied the law governing claim construction to the undisputed facts of the structure described in the specification.

On the correct claim construction the written description is in accordance with and in support of the claims. The judgment of invalidity on this ground is reversed.

B. Anticipation

The jury also found claims 15 and 16 invalid based on anticipation. "Anticipation" requires that the identical invention was already known to others, that is, that the claimed invention is not new. See *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1572, 24 USPQ2d 1321, 1332 (Fed. Cir. 1992) ("In order to anticipate, the [reference] must sufficiently describe the claimed invention to have placed the public in possession of it.") M3 Systems argued that anticipation arose on the published PCT application describing the first generation biopsy gun, and on the device itself. It was not disputed, however, that the first generation gun lacks the integrated mechanical energizing structure described and claimed in the '308 patent, and that the PCT application does not show such structure.

M3 Systems' argument was that when the claims are correctly construed they are anticipated. M3 states that on the claim construction reached by the jury in finding claims 15 and 16 unsupported by the written description, whereby the term "sequential" is defined as barring all overlap in needle movement, the structure in the specification is inconsistent with the claims and

therefore must be disregarded. M3 argues, as we understand it, that since "energizing means" and "sequential energizing means" are in means-plus-function form, it is appropriate to disregard the structure in the specification that is inconsistent with the claim language, leaving the claimed functions with " no disclosed supporting structure," quoting from M3's brief. Thus, according to M3, these claim terms are directed only to function, and can be anticipated by any prior art that shows the function of energizing or sequential energizing, without limit to how that function is performed. Thus M3 argues that since the PCT application and the first generation gun are manually sequentially energized, one spring at a time, the jury correctly found anticipation by the first generation gun and the PCT application.

Indeed, the jury verdicts can be understood only if one adopts so tortured a view of the law. As we have discussed, it is incorrect to construe claims contrary to the specification, and it is incorrect to construe terms in means-plus-function form as disembodied from the structure in the specification. M3 Systems' witnesses readily admitted that the integrated mechanized gun described and claimed in the '308 patent is different from the first generation gun and the description of that gun in the PCT application. On the undisputed facts and the correct law, a reasonable jury could not have found the '308 claims anticipated thereby. The judgment of invalidity for anticipation must be reversed.

C. *Obviousness*

M3 Systems argues that the third generation gun of the '308 patent would have been obvious in view of the PCT application and the first generation gun, in combination with the '154 patent describing the second generation gun. M3 states that the third generation is an obvious combination of elements found in the first and second generations. See discussion, Part I.B. *ante*, of the law of obviousness. There was no dispute as to the scope and content of this prior art, or as to the

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elements in the third generation gun that were not in either the first or second generations. The only dispute was the ultimate question of whether the third generation gun would have been obvious from what had gone before.

M3 Systems contends that for the third generation the inventor simply changed the integrated mechanical cocking mechanism of the second generation gun to accomplish mechanically the sequential cocking that was necessarily done when the first generation gun was manually cocked, one spring at a time. Bard replies that the one-at-a-time cocking of the springs in the first generation, by hand or by miniature crowbar, does not teach or suggest the integrated automatic sequential cocking of the third generation, and that there is no teaching or suggestion in the prior art to make such a combination, or of the structure having the improved ease of handling of the third generation gun. Bard also points to the other new structural features of the third generation whereby the needles can be retracted separately after tissue sampling.

The ultimate question is whether, from the evidence of the prior art and the knowledge generally available to one of ordinary skill in the relevant art, there was in the prior art an appropriate teaching, suggestion, or motivation to combine components in the way that was done by the inventor. See, e.g., *Uniroyal*, 837 F.2d at 1050, 5 USPQ2d at 1438; *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). The ultimate determination of obviousness is a legal conclusion. When this legal conclusion is drawn by the jury the verdict is reviewed, as discussed in Part I.B, to determine whether substantial evidence supports the factual findings necessary to support the legal conclusion, with due consideration to the presumption of validity and the standard of proof.

[6] Bard points out that its rotating sleeve mechanism for sequential energizing is a marked distinction from its earlier devices, even were the concept of sequential energizing deemed to be derivable from the manual operation of the first generation. M3 Systems does not cite any reference suggesting the structure employed in the third generation gun, or any suggestion of mechanical sequential energizing, or indeed the other features of the third generation. Those contributions came from the inventor, not the prior art. See *Uniroyal*, 837 F.2d at 1050, 5 USPQ2d at 1438. We have been directed to no teaching or suggestion of this combination in the descriptions of the first and second generation guns, viewed separately or together. Thus the verdicts of invalidity on the ground of obviousness are without essential factual support, and can not stand.

IV

INFRINGEMENT OF THE '308 PATENT

The jury found that M3 Systems did not infringe claims 15 and 16 of the '308 patent. Because the special verdicts discussed in Part III.A (that there is not support for these claims in the written description) require an incorrect claim construction, we have reviewed the verdicts of noninfringement on the correct construction, *i.e.*, that claims 15 and 16 do not require a total absence of overlap in the sequential movement of the needles during energizing. Bard contends that on the correct claim construction the verdicts of noninfringement can not stand. Bard is entitled to a new trial if a jury reasonably could have reached verdicts of infringement upon correct claim construction and correct application of the law of infringement. However, if only one result is supportable in law and on undisputed facts, judgment as a matter of law is appropriate. See *Strattec*, 126 F.3d at 1419, 44 USPQ2d at 1036.

On appeal Bard argues only the issue of sequential energizing, asserting literal infringement under section 112 paragraph 6. M3 Systems does not dispute, and indeed emphasizes, that in its ProMag devices there is sequential energizing with a slight overlap in needle movement. However, M3's performance of the function of sequential energizing was not the only disputed issue with respect to infringement. M3 also points out that its device is a box-type biopsy gun and does not contain a "guide sleeve" as required by the claims, and that the M3 ProMag guns use linear tensioning whereas the '308 device performs counter-rotational tensioning, such that the structure used by M3 is not equivalent to that shown in the '308 specification, applying section 112 paragraph 6 to the energizing means of the '308 claims.

M3 Systems states that the '308 patent draws a distinction between box-type biopsy guns such as those made by M3 wherein the housing is merely a container for the device, and guns embodying a mechanism wherein the guide sleeve and a tensioning sleeve interact and serve as part of the cocking mechanism. M3 argued at trial that its housing is independent, whereas in the '308 specification the gun is housed in a two-part structure

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wherein the inner part is the guide sleeve and the outer part is the tensioning sleeve and rotates about the inner part. These sleeves bear cam surfaces and slots that interact with the flanges on the needle heads and thus serve as part of the cocking mechanism. M3 states that its gun has neither a guide sleeve nor a tensioning sleeve, and that its housing is merely the container for the device, and is unconnected with the cocking mechanism.

Although the claims in suit do not require a tensioning sleeve, see *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574, 225 USPQ 236, 239 (Fed. Cir. 1985) (improper to import limitation

from one claim into another claim lacking the limitation), the guide sleeve is described in the specification as "the inner sleeve or guide sleeve." The specification shows and the claims require that the guide sleeve perform a guiding function for the cocking mechanism. Bard does not assert that such a structure is found in the M3 guns. Nor does Bard raise on this appeal any issue of equivalency under the doctrine of equivalents.

At the trial the parties presented evidence on how the patented and accused devices worked, and the court instructed the jury as to the applicable law of infringement of means-plus-function claims. For the energizing means Bard was required to establish, by a preponderance of evidence, that M3 Systems' device embodies the structure described in the '308 specification or an equivalent thereof. 35 U.S.C. Section 112 Para.6; *Valmont Indus., Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1041-42, 25 USPQ2d 1451, 1453-54 (Fed. Cir. 1993); *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1562-63, 231 USPQ 833, 834-35 (Fed. Cir. 1986). Since the structure of the M3 energizing means is not the same as that described in the '308 specification, the issue was whether the structures are equivalent. See *D.M.I.*, 755 F.2d at 1575, 225 USPQ at 239 (" [T]he sole question is whether the single means in the accused device which performs the function stated in the claim is the same as or an equivalent of the corresponding structure described in the patentee's specification as performing that function.") The determination of infringement under section 112 paragraph 6 is a factual question. *In re Hayes Microcomputer Prods. Inc. Patent Litig.*, 982 F.2d 1527, 1541, 25 USPQ2d 1241, 1251 (Fed. Cir. 1992); *Intel Corp. v. United States Int'l Trade Comm'n*, 946 F.2d 821, 841, 20 USPQ2d 1161, 1178 (Fed. Cir. 1991); *D.M.I.*, *supra*.

There was no dispute that the function of sequential energizing is performed in the M3 Systems' guns; the only question was whether the M3 guns employ the same or an equivalent of the structure described in the '308 specification. The accused equivalent structure need not have been known at the time the patented invention was made. See *Texas Instruments*, 805 F.2d at 1563-64, 231 USPQ at 834-35 ("It is not required that those skilled in the art knew, at the time the patent application was filed, of the asserted equivalent means of performing the claimed functions. . . .")

It was explained at trial that to achieve sequential energizing in the '308 device the outer tensioning sleeve is rotated about the inner guide sleeve; cam surfaces on the interior of the tensioning sleeve push against wings built directly into the needle heads to compress the two springs in sequence, pressing them rearward into the locked position. In contrast, in the M3 Systems device a handle connected through the rear of the housing acts on sleds bearing the needles; M3's device relies on the lever-action of the handle, as opposed to a rotating sleeve, to pull, rather than push, the needle sleds sequentially back toward their respective latches. Bard had argued at trial, in connection with the issue of validity, that the claims "must be interpreted as means-plus-function terms in accordance with *Valmont*," and cited its "external integrated energizing mechanism that converts rotary motion to linear motion" to distinguish the '308 gun from its own earlier device. Claims must be interpreted the same way for determining infringement as was done to sustain their validity.

[7] A reasonable jury could have found that the structure using rotational tensioning as the energizing means is substantially different from the energizing structure in the M3 Systems guns. Although Bard argues that it suffices for infringement if the energizing is achieved with the slight overlap shown in the '308 patent, that is, if the function of sequential energizing is performed, claims written in the form authorized by section 112 paragraph 6 are limited by the structure described and equivalents of that structure. Performance of the same function does not of itself establish infringement.

Bard directs us to the doctrine of claim differentiation, and argues that it is incorrect to interpret

the "sequential energizing means" of claim 15 as limited to the structure in the specification, because other claims, not at issue, specifically state that structure. Bard argues that its claims in suit are broader in that they state only the function of sequential energizing, and that they therefore warrant broader scope than the

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claims that state a specific energizing structure. However, as we have discussed, claims that are written in the form authorized by section 112 paragraph 6 are by statute limited to the structure described in the specification and equivalents of that structure. As discussed in *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538, 19 USPQ2d 1367, 1371 (Fed. Cir. 1991) a "means-plus-function limitation is not made open-ended by the presence of another claim specifically claiming the disclosed structure which underlies the means clause or an equivalent of that structure."

Applying this law, and based on the absence of a guide sleeve or any counterpart structure, and the differences in the structures of the energizing mechanisms, we conclude that on the correct claim interpretation a reasonable jury could find that claims 15 and 16 are not infringed. The judgment of noninfringement of the '308 patent is affirmed.

V

FRAUD

M3 Systems charged that Bard had committed both fraud and inequitable conduct in prosecuting the '056 and '308 patents. The jury was not asked to decide the issue of inequitable conduct, which was reserved to the judge and withdrawn by M3 after the favorable verdicts on the question of fraud. The jury found that it had been established by clear and convincing evidence that each of the '056 and the '308 patents had been procured by fraud in the Patent and Trademark Office.

Fraud in the procurement of a patent requires proof of the elements of fraud as developed in the common law: (1) that a false representation of a material fact was made, (2) with the intent to deceive, (3) which induced the deceived party to act in justifiable reliance on the misrepresentation, and (4) which caused injury that would not otherwise have occurred. See *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-70, 46 USPQ2d 1097, 1105-06 (Fed. Cir. 1998); *Norton v. Curtiss*, 433 F.2d 779, 792-94 & n.12, 167 USPQ 532, 543-45 & n.12 (CCPA 1970) (citing W. Prosser, *Law of Torts* Sections 100-05 (3d ed. 1964)).

The tort of fraud requires that there was a successful deception, and action taken by the person deceived that would not have otherwise been taken. Applied to patent prosecution, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted. A finding of fraud can of itself render the patent unenforceable, and when accompanied by the elements of violation of the Sherman Act, as discussed in Part VI, can incur additional consequences.

To establish fraud for purposes of antitrust violation the defendant "must make a greater showing of scienter and materiality" than when seeking unenforceability based on conduct before the Patent Office. 6 Donald S. Chisum, *Chisum on Patents* Section 19.03[6] [e] (rel. 47 1993) (citations omitted). In *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177, 147 USPQ 404, 407 (1965) the Court clarified that "knowing and willful" fraud

must be shown, and is predicate to potential antitrust violation. As explained in *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 996, 202 USPQ 342, 351 (9th Cir. 1979), "[t]he road to the Patent Office is so tortuous and patent litigation is usually so complex, that 'knowing and willful fraud' as the term is used in *Walker* can mean no less than clear, *convincing proof of intentional fraud involving affirmative dishonesty*, 'a deliberately planned and carefully executed scheme to defraud * * * the Patent Office.' . . . Patent fraud cases prior to *Walker* required a rigorous standard of deceit *Walker* requires no less." (Emphasis and elisions in original.) The requirements of common law fraud are in contrast with the broader sweep of "inequitable conduct," an equitable defense that may be satisfied when material information is withheld with the intent to deceive the examiner, whether or not the examiner is shown to have relied thereon. See *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988).

M3 Systems stated that Bard made myriad material misrepresentations in prosecuting the '056 and the '308 patents, including the following: the incorrect inventors were named; actual samples of the Tru-Cut needles and the first generation device were not provided to the examiner; the Baxter patent on the Tru-Cut needle and two Lindgren articles on the first generation device were not provided to the examiner; the material submitted to the FDA was not provided to the examiner; the examiner was not told of the co-pending design patents; and the examiner was not provided with all of the evidence on the on-sale issue. Bard responded that

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there is no substance to any of these assertions; that all material information was presented to the examiner; that there was no intent to deceive the examiner; that the examiner was not deceived; and that the evidence points to good faith in the prosecution of these patents. Good faith is an absolute defense to the charge of common law fraud. See *Walker Process*, 382 U.S. at 177, 147 USPQ at 407.

[8] M3 Systems argues that any omission in the submissions to the PTO is "necessarily material, because the allowance of the application is the intended natural consequence of that submission." That is not a correct statement of the law. There is no presumption that information not filed by an applicant was material simply because patentability ensued. To establish culpability any omission must be of a fact material to patentability and it must be a deliberate misrepresentation, whether by omission or misstatement, that was intended to and did mislead the examiner into taking favorable action that would not otherwise have been taken. Intent to mislead or to deceive must be proved by clear and convincing evidence. See *Walker Process*, *supra*. Deceptive intent is not inferred simply because information was in existence that was not presented to the examiner; and indeed, it is notable that in the usual course of patent prosecution many choices are made, recognizing the complexity of inventions, the virtually unlimited sources of information, and the burdens of patent examination. See *Northern Telecom*, 908 F.2d at 939, 15 USPQ2d at 1327 (discussing the ease with which routine patent prosecution may be portrayed as tainted conduct).

Following are the actions that M3 Systems presented as probative of fraud in the prosecution of the '056 or the '308 patent:

1. *The Inventorship Issue*

This issue was discussed *ante* in connection with the validity of the '056 patent. There was no evidence of intent to deceive in correcting the inventorship to include Mr. degrees Akerfeldt with Dr. Lindgren as joint inventors. The question of Mr. Taylor's role as a possible inventor did not present substantial evidence of fraud. Indeed, since the inventorship issue was not grounds

of invalidity, it can not satisfy the "but for" test of fraud.

2. Provision of Actual Models to the Examiner

M3 Systems argued that Bard should have provided the reissue examiner with actual models of the first generation gun and the Tru-Cut needles, in addition to the PCT application and publications describing the needles. The PCT application described the first generation gun, and descriptions of the Tru-Cut needles were before the examiner. Reviewing the prosecution history we do not discern substantial evidence of material withholding, for cumulative information is not material to patentability, and there was no evidence of deceptive intent or that the examiner was deceived into granting the reissue. This issue can not support the verdict of fraud.

3. Provision of On-Sale Information to the Examiner

Bard filed with the PTO descriptions of the transactions involving Radiplast and Pharmaseal before the critical date, accompanied by documents including the invoice for the 10 guns and 250 needles for the clinical trials, the bulk price quotation discussed *ante* in connection with the on-sale issue, and declarations concerning the hospital tests and the proposed distribution relationship between Radiplast and Pharmaseal. M3 Systems states that Bard should have also disclosed to the PTO Radiplast's sales activities for the first generation device, Radiplast's letters to doctors concerning the clinical trials, the fact that the bulk price quotation included a profit, and Radiplast's letter to Dr. Phelps.

Concerning Dr. Phelps, Bard answers that it submitted to the PTO all the relevant material it had obtained. The letter to Dr. Phelps was obtained after suit was filed, during discovery of Radiplast's files in Sweden. There was no evidence that Bard had obtained and withheld this information during the reissue prosecution. With respect to the bulk price quotation, M3 Systems states that Bard should have flagged this document and described its significance to the examiner, lest it be overlooked in the volume of paper. Bard responds that the documents provided to the examiner were a record of Radiplast's efforts to find a distributor and its transactions with Pharmaseal, and that the total number of documents was not so voluminous, or the contents so difficult to understand, as to support an inference of intentional concealment of any particular document that was filed. We agree that these documents, all in the prosecution history, are easily read.⁶

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On reviewing these filings in the PTO we have been directed to no evidence of material withholding or the provision of false information, or of intent to deceive or actual deception. The additional subject matter that M3 states should have been included was not shown to be material or other than cumulative. These actions did not constitute substantial evidence of fraud.

4. Disclosure of the Information Filed with the FDA

None of the material provided us with respect to Radiplast's 510(k) pre-market notification filed with the Food & Drug Administration supports a finding of fraud in the patent prosecution. M3 Systems concentrates on the presence in this package of needle drawings made by Hart Enterprises, the designated manufacturer. As we have explained, the inventorship issues that have been raised do not provide substantial evidence of fraudulent procurement of these patents.

5. Disclosure of the PCT Application

The PCT application had been submitted to the PTO during prosecution of the '154 patent and again during the '056 reissue proceedings. M3 Systems states that Bard withheld the PCT application from the examiner of the '308 patent and then mischaracterized it.

M3 Systems stated at trial and repeats on this appeal that Bard submitted the PCT application to

the examiner of the '308 patent only after allowance of the '308 claims in suit, and then falsely represented that it was relevant solely to newly added claims 21-23 (as then numbered). Bard complains that M3 misstated at trial, and continues to misstate, these facts. We must agree. The '308 prosecution history in the record shows that Bard cited the PCT application and filed a copy thereof with a Supplemental Information Disclosure Statement accompanying Bard's first response, filed October 13, 1989, to the first Office Action. Contrary to M3's statements, the prosecution record shows that no claims had been allowed or held allowable when the PCT application was submitted to the PTO.

In submitting the PCT Application Bard's patent attorney pointed out the aspect of that application that M3 Systems has stated is of greatest significance, *viz.*, the separate and thus sequential hand cocking of the springs in the first generation device. In the Remarks section of the response Bard discussed claims 21-23, the claims specific to sequential energizing. We discern no support for M3's argument that Bard misrepresented the content of the PCT application, or that the examiner did not consider the PCT application adequately. The examiner initialed on December 15, 1989 that he had considered this reference, the same day a telephone interview was held that led to an examiner's amendment, followed by allowance on January 3, 1990. The charge of fraud based on these events is totally without substance.

Conclusion

These asserted flaws in patent prosecution, separately or taken together, do not constitute substantial evidence of fraud. The verdicts of fraud in procuring the '056 and '308 patents can not stand, and the judgment on these verdicts is reversed.

VI

ANTITRUST ISSUES

Antitrust violation was found on special verdicts that Bard by anticompetitive conduct had monopolized or attempted to monopolize the relevant markets for each of fully automated biopsy guns and needles, guns alone, and replacement needles. The jury instructions on the antitrust count identified three separate claims; first, that the patents were procured by fraud followed by attempts to enforce the fraudulently procured patents; second, that Bard threatened and then brought suit knowing that its patents were invalid, unenforceable, or not infringed; and third, that Bard unlawfully leveraged its monopoly power in the guns to obtain a competitive advantage in replacement needles by modifying its gun to accept only Bard needles. The jury found in favor of M3 Systems and against Bard on every question, and assessed compensatory damages, measured primarily as litigation costs, of \$1.5 million, which were trebled as required by section 4 of the Clayton Act. Bard argues that the findings are not supported by substantial evidence, and that judgment as a matter of law should have been granted.

A. The Walker Process Claim

Fraud in obtaining a United States patent is a classical ground of invalidity or unenforceability

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of the patent. In *Walker Process*, 382 U.S. 172, 147 USPQ 404 the Court established that antitrust liability under section 2 of the Sherman Act may arise when a patent has been procured by knowing and willful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition. Restraint on competition based on power in the relevant market must be established on the criteria of section 2, when the patent has been fraudulently obtained. See *Nobelpharma*, 141 F.3d at 1068, 46 USPQ2d at 1104; 7

Spectrum Sports, Inc. v. McQuillan , 506 U.S. 447, 455-56 (1993) (explaining *Walker Process* as requiring appraisal of the exclusionary power of the fraudulently obtained patent in terms of the relevant market for the product involved).

The jury found by special verdicts that the '056 and '308 patents were obtained by fraud in their prosecution before the PTO, as discussed in Part V, *ante* . The jury also found that "there is a relevant product market" for the biopsy guns and needles, together and separately, that Bard had monopoly power in each market and had "engaged in restrictive or exclusionary conduct with the conscious object of acquiring monopoly power in that market."

[9] It is not presumed that the patent-based right to exclude necessarily establishes market power in antitrust terms. See *Abbott Labs. v. Brennan* , 952 F.2d 1346, 1354, 21 USPQ2d 1192, 1199 (Fed. Cir. 1991) (possession of patent, and market advantages thus gained, do not establish antitrust market power). The virtually unlimited variety and scope of patented inventions and market situations militate against per se rules in these complex areas. Unless the patent had been obtained by fraud such that the market position had been gained illegally, the patent right to exclude does not constitute monopoly power prohibited by the Sherman Act. *Walker Process* , 382 U.S. at 177-78, 147 USPQ at 407. As the Second Circuit stated in *SCM Corp. v. Xerox Corp.* , "No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant product market." 645 F.2d 1195, 1204, 209 USPQ 889, 899 (2d Cir. 1981).

[10] Thus it was necessary for M3 Systems to establish market power as well as fraudulent procurement of the patent and that Bard's related commercial activity was coupled with violations of section 2. In addition, applying the law of the Seventh Circuit to the elements of section 2, M3 was required to establish that Bard had a specific intent to monopolize, engaged in anti-competitive conduct, and had a dangerous probability of success. See *Great Escape, Inc. v. Union City Body Co.* , 791 F.2d 532, 540 (7th Cir. 1986). These issues were argued at trial, and by special verdicts the jury found culpability on the part of Bard. However, in view of the incorrect verdicts on the question of fraud in procurement of the '056 and '308 patents, as discussed in Part V, as a matter of law the judgment of antitrust violation can not be sustained on *Walker Process* grounds.

B. "Sham" Litigation

Conduct prohibited under antitrust law includes bringing suit to enforce a patent with knowledge that the patent is invalid or not infringed, and the litigation is conducted for anti-competitive purposes. In such events the antitrust immunity of *Noerr - Pennington* and *California Motor Transp. Co. v. Trucking Unltd.* , 404 U.S. 508 (1972) does not apply to those who seek redress through judicial process.

The Supreme Court in *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* (*PRE*) established the two-part criteria of "sham" litigation: (1) the lawsuit must be objectively meritless such that "no reasonable litigant could expect success on the merits" and (2) it must be found that "the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" 508 U.S. 49, 60, 26 USPQ2d 1641, 1646 (1993) (emphasis in original) (quoting *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.* , 365 U.S. 127, 144 (1961)). The Court declined to decide "whether and, if so, to what extent *Noerr* permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations." *PRE* , 508 U.S. at 62 & n.6, 26 USPQ2d at 1646-47 & n.6. Fraud in the procurement of a patent is governed by *Walker Process* and, as in *PRE* , the complainant "must still prove a substantive antitrust violation." *PRE* , 501 U.S. at 61, 26 USPQ2d at 1646.

Thus although sham litigation as a tactic to destroy competition can lead to antitrust violation, see *U.S. Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 597, 34 USPQ2d 1699, 1703 (Fed. Cir. 1995); cf. *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1288, 223 USPQ 214, 222-23 (9th Cir. 1984) (addressing *Noerr - Pennington* issue and explaining that to invoke "sham" exception the claimant must show "some abuse of process," and requiring clear and convincing evidence of bad faith), sham litigation requires more than a failed legal theory. *PRE*, 508 U.S. at 60-61 & n.5, 26 USPQ2d at 1646 & n.5; see *Carroll Touch, Inc. v. Electro-Mechanical Sys., Inc.*, 15 F.3d 1573, 1582, 27 USPQ2d 1836, 1844 (Fed. Cir. 1993). [11] Neither the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability. Cf. *Concrete Unltd. Inc. v. Cementcraft, Inc.*, 776 F.2d 1537, 1539, 227 USPQ 784, 785 (Fed. Cir. 1985) (no liability for unfair competition based on suit to enforce an invalid patent). Since a principal purpose of the patent system is to provide innovators with a property right upon which investment and other commercial commitments can be made, absent the *PRE* criteria the patentee must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent's validity or infringement not survive litigation. See *id.* The law recognizes a presumption that the assertion of a duly granted patent is made in good faith, see *Virtue v. Creamery Package Mfg. Co.*, 227 U.S. 8, 37-38 (1913); this presumption is overcome only by affirmative evidence of bad faith. See *PRE*, *supra*.

M3 Systems states that Bard knew its patents were not infringed when it brought suit, citing the testimony of a Bard engineer that he did not think the original M3 needle infringed the '056 patent and that other Bard employees had told him that M3 changed its needle design to one that did not infringe. The engineer also testified that he did not know whether those who told him M3's needles did not infringe had ever read the '056 patent, or whether they were familiar with the concept of infringement under the doctrine of equivalents. This was the totality of the evidence of sham litigation concerning the '056 patent; there was no evidence at all with respect to the '308 patent. 8 This does not constitute substantial evidence that this litigation was objectively meritless and brought in bad faith. The judgment of antitrust violation can not be upheld on sham litigation grounds.

C. Attempt to Monopolize 9

M3 Systems proposed that Bard had modified its biopsy gun and needles for the purpose of preventing use of Tru-Cut needles and then to exclude M3's copies so that they did not fit the gun without an adapter. M3 contends that Bard's motives were anti-competitive, pointing to Bard documents showing internal discussions of competitive products and concern for patent scope and market share. Bard replies that the Tru-Cut was not suitable for its new gun because it could not achieve reverse motion, and points out that M3's witness acknowledged that M3 could effectively compete, as were several other producers of biopsy guns and needles.

Bard was under no duty to facilitate M3's competition by refraining from changing its products. The jury instructions did not distinguish patent-supported products and markets based thereon from actions described to the jury as being in restraint of trade. For example, the jury instruction on intent to monopolize was as follows:

M3 Systems also alleges that it was injured by Bard's unlawful attempt to monopolize. An attempt to monopolize may be proven even if Bard lacks monopoly power, but because of its alleged exclusionary conduct, there exists a dangerous probability that Bard will obtain monopoly power in any market. In order to win on its claims of attempted monopolization, M3

Systems must prove each of the following elements by a preponderance of the evidence: First, that Bard had a specific intent to achieve monopoly power in a relevant market; second, that Bard engaged in exclusionary or restrictive conduct in furtherance of its specific intent; third, that there

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was a dangerous probability that Bard would obtain monopoly power in the relevant market; and, fourth, that M3 Systems was injured in its business or property by Bard's conduct. In explaining further, the district court referred to "exclusionary or restrictive conduct" and "unreasonable acts and practices," again without reference to patented products and their status in the law. Although the court instructed that "conduct that involves the introduction of superior products" is not exclusionary or restrictive, the court also stated that "where conduct is ambiguous, direct evidence of a specific intent to monopolize may lead you to conclude that the conduct was intended to be and was in fact exclusionary or restrictive." No mention was made of the patentee's statutory right to exclude, and there was no instruction to consider that right.

These broadly stated descriptions of exclusionary or restrictive conduct, unlimited by the conditions set in *Walker Process* or *PRE* and taking no cognizance of the legal rights of the patent grant, do not rise to the level of violation of antitrust law. Thus I must, respectfully, dissent from the court's ruling that Bard incurred liability under the Sherman and Clayton Acts by its actions in modifying and improving its patented products, thereby requiring M3 to provide an adapter with its replacement needles for the Bard gun.

The panel majority on this issue holds that the jury verdict of monopoly power must be sustained, although the power held by Bard in this market is based on the patent right. Bard or its predecessor Radiplast changed from the Tru-Cut to a newly designed needle that was capable of reverse movement, thus facilitating removal, inspection, and reinsertion of the inner needle while the cannula remained in place. This needle assembly is the subject of the '056 patent. The record states that M3 was obliged to use an adapter to fit its existing needles to Bard's gun; that is the antitrust ill of which M3 complained. This does not, as a matter of law, present a jury question of violation of the Sherman Act. See *California Computer Prods., Inc. v. International Bus. Mach. Corp.*, 613 F.2d 727, 744 (9th Cir. 1979) (when the innovation is an improvement, that it affects competition is not an antitrust violation, and no jury question arises).

Both the needle assembly alone and the integrated biopsy gun/needle device were patented. They were subject to Bard's patent-based rights to exclude others from making, using, or selling them. It was not Bard's changes to its biopsy gun or needles that affected M3's sale of replacement needles; it was the patents on these products. To hold that Bard could violate the Sherman Act by changing these products, if M3's business was adversely affected, is a novel and pernicious theory of antitrust law that is contrary to the principles of competition, and fraught with litigation-generating mischief.

Despite this court's recent affirmation in *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 873-74, 45 USPQ2d 1225, 1236 (Fed. Cir. 1997) that "a patentee may lawfully police a market that is effectively defined by its patent," this court now holds that changing and improving one's proprietary product that has created its own market niche, if to a competitor's potential disadvantage, is actionable under the Sherman Act. The competition-favoring rule is that an innovator has no duty to help its competitors: "It is the possibility of success in the marketplace, attributable to superior performance, that provides the incentives on which the proper functioning of our competitive economy rests." *Berkey Photo, Inc. v. Eastman Kodak*

Co. , 603 F.2d 263, 281 (2d Cir. 1979). In *California Computer* the court observed that "[IBM] was under no duty to help CalComp or other peripheral equipment manufacturers survive or expand." 613 F.2d at 744. This court has today created a new, vague, and unworkable cause of action, of clear public detriment, with no balancing public benefit.

The concept that antitrust law should bar an innovator from making changes or improvements to its products, when others may be affected thereby, is not brand new. However, cases where this issue has been litigated have been of a different order of competitive impact than here asserted; and I have found no case in which such a charge has been sustained. In *In re IBM Peripheral EDP Devices Antitrust Litig.* , 481 F. Supp. 965, 1002-05 (N.D. Cal. 1979), *aff'd sub nom. Transamerica Computer Co. v. International Bus. Mach. Corp.* , 698 F.2d 1377 (9th Cir. 1983), cited by the panel majority, the district court declined to assess liability for IBM's interface changes that prevented use of competitors' peripheral devices when "the contested changes were improvements in the products, were not unreasonably restrictive of competition, and hence did not violate the Sherman Act." *Id.* at 1382.

A basic premise of patent law, and antitrust law in general, is that the commercial advantage gained by new technology, and its statutory protection by patent, do not convert the possessor thereof into a prohibited monopolist. In *United States v. Grinnell*

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Corp. , 384 U.S. 563, 570-71 (1966) the Court distinguished the willful acquisition or maintenance of monopoly power from "growth or development as a consequence of a superior product, business acumen, or historic accident." See also *Jefferson Parish Hospital District No. 2 v. Hyde* , 466 U.S. 1, 37 n.7 (1984) ("A common misconception has been that a patent or copyright, a high market share, or a unique product that competitors are not able to offer suffices to demonstrate market power.") (O'Connor, J., concurring); *A.I. Root Co. v. Computer/Dynamics, Inc.* , 806 F.2d 673, 676 (6th Cir. 1986) (rejecting "any absolute presumption of market power for copyright or patented product").

When the market for new technology is protected by patent, to violate the antitrust law there must be an improper use of the patent right, "coupled with violations of Section 2." *Walker Process* , 382 U.S. at 177-78, 147 USPQ at 407. In *Walker Process* the Court again explained that a patent does not of itself establish a presumption of market power in the antitrust sense. *Id.* at 178, 147 USPQ at 406. In *American Hoist & Derrick Co. v. Sowa & Sons, Inc.* , 725 F.2d 1350, 1367, 220 USPQ 763, 776 (Fed. Cir. 1984), this court wrote that "patent rights are not legal monopolies in the antitrust sense of the word." Yet in the case now before us the jury was asked to determine simply whether Bard had monopoly power in a relevant market, without reference to whether the "exclusionary conduct" of which M3 complained was the conduct of the patent law.

M3 did not allege the elements of an antitrust violation when patents are involved. See , e.g. , *Double D Spotting Service, Inc. v. Supervalu, Inc.* , 136 F.3d 554, 558 (8th Cir. 1998) ("The essential elements of a private antitrust claim must be alleged in more than vague and conclusory terms to prevent dismissal of the complaint on a defendant's [Rule] 12(b)(6) motion.") (quoting *Crane & Shovel Sales Corp. v. Bucyrus-Erie Co.* , 854 F.2d 802, 805 (6th Cir. 1988)); *Okusami v. Psychiatric Institute of Washington, Inc.* , 959 F.2d 1062, 1065 (D.C. Cir. 1992) ("[T]he plaintiff's antitrust claims, lacking the essential element of an agreement, were properly dismissed for failure to state a claim upon which relief could be granted.") Dismissal for failure to state a claim was the proper response to M3's undifferentiated assertion of anticompetitive practices.

I need not elaborate on the litigation opportunity affecting innovation-based industry, that is here so casually enabled. "Where competitors' products must interface with the monopolist's product the monopolist's introduction of a new product that makes that interconnection more difficult or expensive might violate Section 2, although *no court has specifically so held* ." 1 American Bar Assoc., *Antitrust Law Developments* 286 (4th ed. 1997) (emphasis added). As a sister circuit recently stated, "Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law." *United States v. Microsoft Corp.* , 147 F.3d 935, 948 (D.C. Cir. 1998).

The proceedings at trial, and the jury instructions, made no mention of the patent rights here present. It is without precedent to find antitrust liability premised on a theory that development of new products is illegally anticompetitive when the new product requires competing suppliers to adjust their product accordingly. Commentators who have considered the question of "whether product innovation can ever be unlawfully 'predatory' " have concluded that "no administrable rule could be fashioned that would not exact an unreasonably heavy toll." 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* Section 705b (rev. ed. 1996). If this court deems it appropriate to add this burden to patent-based innovation, there should at least be some overriding public benefit. However, antitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation. See *IBM Peripherals* , *supra* .

Neither the jury instructions nor the special interrogatories framed a charge of predatory conduct that comports with established criteria of antitrust liability. It appears that this charge at trial was cobbled together from left-over allegations of bad acts by bad actors. Indeed, M3's antitrust counterclaims mention only *Walker Process* fraud and sham litigation, which all members of this panel agree were not established. I can not discern, in the law or in the record of this case, either legal or factual support for this new form of antitrust liability.

VII

MISUSE; OTHER ISSUES

The defense of patent misuse arises from the equitable doctrine of unclean hands, and relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage. Patent misuse relates primarily to a patentee's actions that affect competition in unpatented goods or that otherwise

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extend the economic effect beyond the scope of the patent grant. See *Mallinckrodt, Inc. v. Medipart, Inc.* , 976 F.2d 700, 703-04, 24 USPQ2d 1173, 1176 (Fed. Cir. 1992) ("The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that draw anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.")

Patent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee's right to exclude. Thus misuse may arise when the conditions of antitrust violation are not met. See *Zenith Radio Corp. v. Hazeltine Research, Inc.* , 395 U.S. 100, 140-41, 161 USPQ 577, 597 (1969). The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect. See *Virginia Panel*

Corp. v. MAC Panel Co. , 133 F.3d 860, 868, 45 USPQ2d 1225, 1231-32 (Fed. Cir. 1997); *B. Braun Medical, Inc. v. Abbott Labs.* , 124 F.3d 1419, 1426, 43 USPQ2d 1896, 1902 (Fed. Cir. 1997); *Mallinckrodt* , 976 F.2d at 704, 24 USPQ2d at 1176.

The jury returned special verdicts that Bard had misused both the '056 and '308 patents. Patent misuse arises in equity, and a holding of misuse renders the patent unenforceable until the misuse is purged; it does not, of itself, invalidate the patent. See *Morton Salt Co. v. G. S. Suppinger Co.* , 314 U.S. 488 [52 USPQ 30] (1942); *Senza-Gel Corp. v. Seiffhart* , 803 F.2d 661, 668 n.10, 231 USPQ 363, 368 n.10 (Fed. Cir. 1986). When a jury has determined that patent misuse occurred we review the underlying findings of fact for support by substantial evidence, presuming that the jury resolved any factual disputes in favor of the verdict winner. We then determine whether, on the found or presumed facts, the conclusion on the issue of misuse is correct. See *Virginia Panel* , 133 F.3d at 868, 45 USPQ2d at 1231-32.

The jury instruction on patent misuse was focussed primarily on the charge that Bard was attempting to enforce the patents against goods known not to be infringing, the court explaining that antitrust violation is not necessary to find misuse if patents have been used "wrongfully" to exclude competitors:

A patent is unenforceable for misuse if the patent owner attempts to exclude products from the marketplace which do not infringe the claims of the patent and the patent owner has actual knowledge that those products do not infringe any claim of the patents. The patent is also unenforceable for misuse when a patent owner attempts to use the patent to exclude competitors from their marketplace knowing that the patent was invalid or unenforceable,

A patent will not be rendered unenforceable for misuse if the patent owner has enforced the patent in the good faith belief that the accused products infringed the patent's claims.

You may consider all aspects of the conduct of the patent owner in deciding whether a patent has been misused. In order to find misuse, you may not determine that -- you need not determine that an antitrust violation has been proved. Even if an antitrust violation has not been proven, you may still find that the patents have been misused if you conclude that the patents have been used wrongfully.

This instruction calls to mind the view expressed in *USM Corp. v. SPS Techs., Inc.* , 694 F.2d 505, 510, 216 USPQ 959, 963 (7th Cir. 1982) that the misuse doctrine is "too vague a formulation to be useful." Although the defense of patent misuse indeed evolved to protect against "wrongful" use of patents, the catalog of practices labelled "patent misuse" does not include a general notion of "wrongful" use. See *id.* ("in application, the doctrine has largely been confined to a handful of specific practices").

M3 Systems did not propose any of the classic grounds of patent misuse, such as tying or enforced package licensing or price restraints or extended royalty terms, see *Chisum, supra* , Section 19.04 [3], but generally urged the view that Bard's actions, even if not illegal, were an improper use of patents. Although the law should not condone wrongful commercial activity, the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce.

[12] There was no evidence that Bard's competitive activities were either per se patent misuse or that they were not "reasonably within the patent grant." See *Mallinckrodt* , 976 F.2d at 708, 24 USPQ2d at 1180. The conduct to which the jury instruction on misuse generally refers, that is, "wrongful" enforcement of patents, is activity protected under *Noerr* and *California Motor* , and is not subject to collateral attack as a new ground of "misuse." M3 Systems adduced no evidence of patent misuse other than was presented for its antitrust claims. It is not patent misuse to bring suit to enforce patent rights not fraudulently obtained, nor is otherwise legal competition such behavior as to

warrant creation of a new class of prohibited commercial conduct when patents are involved. The verdicts of patent misuse are not supported by evidence or correct legal theory. The judgment on these verdicts is reversed.

Other Arguments/Issues

We have not discussed every minor argument and issue raised in this appeal. All have been considered, and we have discussed those of relevance. With respect to Bard's frequent references to jury prejudice resulting from disclosure to the jury of Bard's recent civil penalties and criminal convictions for several violations of Food and Drug Administration laws and regulations, we take note that no motion for a new trial was made on this ground, and the issue is not before us for review.

Costs

No costs.

**AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART,
AND REMANDED .**

Mayer, C.J., concurring-in-part and dissenting-in-part.

I join the court's opinion as it pertains to the validity and infringement of the '308 patent, and agree that the jury's verdict on fraud cannot stand. I join Judge Bryson's opinion sustaining the jury verdict on M3's antitrust counterclaim and remanding. My views on the validity of the '056 patent follow.

By special interrogatory, a jury found each of the disputed claims of the '056 patent invalid because the claimed invention was on sale in the United States more than one year before July 30, 1986, the filing date of the '056 patent's parent application. M3 Systems presented the jury with two reasons why the invention may be invalid for violation of the on sale bar: a transfer from Radiplast to Pharmaseal of 250 needles in June 1985 and an offer from Radiplast to Dr. Ronald Phelps in November 1984. We may affirm the invalidity verdict on either basis. See, e.g., *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1582, 40 USPQ2d 1019, 1027 (Fed. Cir. 1996). Because I believe that the jury had substantial evidence that Radiplast placed the invention claimed in the '056 patent on sale in November 1984, I would sustain the jury's verdict of invalidity.

Discussion

An inventor who places his invention "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States" loses his right to patent the invention. 35 U.S.C. Section 102(b) (1994). A determination that a product was placed on sale under section 102(b) is a question of law, based on underlying facts. See, e.g., *KeyStone Retaining Wall Sys. Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1451, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993). While we review the trial court's ultimate determination of a section 102(b) bar *de novo*, see, e.g., *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1515 (Fed. Cir. 1995); *U.S. Environmental Products Inc. v. Westall*, 911 F.2d 713, 715, 15 USPQ2d 1898, 1900 (Fed. Cir. 1990), in considering its denial of Bard's motion for judgment as a matter of law, we review the jury's verdict, as did the trial court, for substantial evidence. See, e.g., *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed. Cir. 1985); *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1513, 220 USPQ 929, 936 (Fed. Cir. 1984). "'Substantial' evidence is such relevant evidence from the

record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp. v. Computervision Corp.* , 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed. Cir. 1984).

We are guided in our review of the legal conclusion by principles underlying the on sale bar: broad and prompt disclosure of inventions to the public; providing opportunity to experiment, improve, and determine the market value of inventions; discouraging inventors from withdrawing inventions that the public has already come to believe are freely available; and discouraging commercialization that expands the patent system's grant of the right to exclude others. *See, e.g. Envirotech Corp. v. Westech Eng'g, Inc.* , 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990); *King Instrument Corp. v. Otari Corp.* , 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985); *General Electric Co. v. United States* , 654 F.2d 55, 61, 211 USPQ 867, 873 (Ct. Cl. 1981). Because the ultimate determination of whether an on sale bar exists rests on the totality of the circumstances, that is, on consideration of the unique facts of each transaction or event, no one factor necessarily controls. *See, e.g. , Ferag* , 45 F.3d at 1566, 33 USPQ2d at 1515. Nevertheless, we have held that " [f]oremost among these is the policy of preventing inventors

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from exploiting the commercial value of their inventions while deferring the beginning of the statutory term. To this end, the inventor is strictly held to the requirement that he file his patent application within one year of any attempt to commercialize the invention." *Ferag* , 45 F.3d at 1566, 33 USPQ2d at 1515 (internal citation omitted). The inventor is entitled to the full benefit of the patent regime; the public is entitled to full, timely disclosure of the protected invention.

We are likewise guided in our review by the principle that we must presume facts necessary to support the jury verdict. *See, e.g. , Perkin-Elmer* , 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics* , 727 F.2d at 1516, 220 USPQ at 939. Given the on sale bar verdict, we assume the jury found that Radiplast made a definite offer to sell certain subject matter and that this subject matter "fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art." *UMC Elec. Co. v. United States* , 816 F.2d 647, 656, 2 USPQ2d 1465, 1472 (Fed. Cir. 1987); *see also LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n* , 958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992). Thus, on review we must affirm the verdict of invalidity of the '056 patent if these factual findings are supported by substantial evidence, and within the context of the various policies underlying the on sale bar, the totality of circumstances supports the ultimate legal conclusion.

I. Offer for Sale

On September 25, 1984, Ronald Phelps, an Alabama medical doctor, sent Radiplast AB a letter that stated: "I am interested in learning more about the new device for percutaneous needle biopsy pictured on the enclosed brochure. I would appreciate it if you would send me all the information you have pertaining to the instrument. Also, please include a price list. Thank you." Phelps included with this letter a brochure entitled "Radi-biopsy device, a new device for percutaneous needle biopsy." This brochure described previously existing technology and then stated:

A new device has been constructed in order to improve this biopsy method. With the aid of this instrument the biopsy procedure can be carried out with one hand, and as the movements of the obturator and cannula are automatized, better tissue specimens are obtained. All biopsies can be performed by one examiner under dynamic ultrasonic control, or under fl [uo]roscopy.

The new device consists of a spring-trigger system for firing the two different parts of the needle -- the cannula and the obturator.

It is constructed of alloyed brass and, like the pressure rod, can be autoclaved.

See special instructions before using.

Manufactured by . . . RADIPLAST AB. . . .

By way of its managing director, Thomas Engstrom, Radiplast, replied as follows to Phelps' letter on November 12, 1984:

We thank you for your letter of [S]ept. 25 [,] 1984 and for your interest in our BIOPSY DEVICE. I am truly sorry for my late reply.

Our generation No. 2 of the device will we, together with our new biopsy needles suitable for the device, start marketing in USA beginning of __85, at the moment we do not know through which company. *If you do not want to wait until we have our representation in USA arranged, you can allways [sic] order the device directly from us.*

Our price for the device is SEK 9.900, -- and for the needles SEK 75, -- /ea.

The device is reusable and can be autoclaved. Very little service has to be done on the device due to reliable design. The needles are disposable and are designed to suit the device.

I am enclosing leaflet and article.

I am looking forward to hearing from you.

(Emphasis added).

The Radiplast brochure that Phelps sent to Radiplast describes a device that can be operated with one hand, by one operator, leaving the physician's other hand free to operate the ultrasound or fluoroscopy equipment. The brochure describes both parts of the needle as automatized by way of a spring-trigger system. It describes the construction materials used to manufacture the device as well as a procedure by which it can be cleaned. In short, the brochure can be understood to describe either a first generation prior art device or the second generation device described in the '056 patent.

Despite this ambiguity, Engstrom's reply to Phelps' letter in November 1984 is far more telling both in what it said and when it said it. His letter explicitly refers to the second generation device and "new biopsy needles suitable for the device." Since the second generation device requires a needle that moves both forward and rearward, unlike the prior art TruCut needle, Engstrom's letter is a clear offer for sale of the second

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generation device and new biopsy needles. With the exception of a reference to marketing efforts being made in the United States and the possibility of sales through a United States distributor thereafter, this letter was written entirely in the present tense.

The letter was also written after a series of correspondence between Radiplast and Hart Enterprises, a United States medical device manufacturer, addressing tooling and manufacturing costs for these new biopsy needles. On September 4, 1984, Engstrom had written: "Enclosed please find . . . a drawing on the biopsy needle. The stainless steel parts are not the final ones, there could be changes in length, diam. and the design of the point." On September 28, 1984, Hart Enterprises responded: "[E]nclosed are two drawings, one of the Stylet Hub and one of the Cannula Hub for your Radiplast Biopsy Needle. If you approve these concepts we will proceed to make a prototype, and then production of the molds." Radiplast replied on October 18, 1984: "Biopsy needles: Enclosed please find our order for tooling and engineering. We approve your design of the plastic parts. The dimension from the top surface to center line of both cannula and stylet should be 4.2 mm. Regarding the needles we will probably start with 2.000 -- 3.000 units

bulk packed." Less than one month later, Engstrom sent Phelps the November 12, 1984, letter.

These facts alone are sufficient support for the jury's verdict that there was a definite offer for sale of something more than the TruCut prior art or first generation needles. However, to apply the on sale bar, the jury also had to decide whether this offer for sale of new biopsy needles was an offer of the invention claimed in the '056 patent. We review this second presumed factual finding for substantial evidence, and like the district court on its denial of Bard's motion for judgment as a matter of law, we also consider whether there may be policy considerations against imposing the on sale bar.

II. Offer of the Claimed Invention

Bard claims that Radiplast's November 1984 offer to sell second generation devices and new biopsy needles cannot trigger the bar because at that time no operable device had been made, FDA approval had not been obtained, Radiplast had not conducted clinical testing, it had not found a United States distributor, and it had not developed a final needle design. Bard misapprehends the legal significance of each of these. Clinical testing is not required before a sale can bar patent rights. Nor can subsequent clinical testing excuse a prior sale, if what was offered for sale was the claimed invention. Clinical testing is merely one possible policy reason why a particular sale might be excused from the bar. Since Radiplast did not contemplate sales to Engstrom for testing purposes, the possibility of subsequent clinical testing is of no moment. Likewise, FDA approval is not required before a sale can bar patent rights. Even an illegal sale of the claimed invention before the critical date can bar patent rights. Nor is a domestic distributor relevant to the on sale bar inquiry; a sale by a foreign distributor, from a foreign country to the United States can bar patent rights. *See, e.g., In re Vaceney*, 761 F.2d 671, 676-77, 226 USPQ 1, 4 (Fed. Cir. 1985).

The first of Bard's two remaining arguments -- that no operable device had been made -- is a feint because manufacture of an operable device is not a prerequisite for application of the on sale bar. *See, e.g., Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 837, 221 USPQ 561, 565 (Fed. Cir. 1984). While operability may or may not be relevant, *see, e.g., UMC*, 816 F.2d at 656, 2 USPQ2d at 1472 (reduction to practice is not a requirement for application of the on sale bar), manufacture of an operable device alone is not, *see, e.g., Continental Plastic Containers v. Owens Brockway Plastic Products, Inc.*, 141 F.3d 1073, 1078-79, 46 U.S.P.Q.2d 1277, 1281 (Fed. Cir. 1998) (declining to extend exception from public use bar under section 102(b) in design patent case). Operability is relevant only to the extent it demonstrates that a claimed element of the invention had not yet been invented, or the inventors did not know they had a workable invention and thus had nothing to offer for sale. *See, e.g., Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 1427, 40 USPQ2d 1201, 1204 (Fed. Cir. 1996) ("[T]he thrust of the on-sale inquiry is whether the inventor thought he had a product which could be and was offered to customers, not whether he could prevail under the technicalities of reduction to practice" (quoting *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1187 n.5, 25 USPQ2d 1561, 1570 n.5 (Fed. Cir. 1993))). Bard has not asserted the second circumstance, and as explained below, the alterations made after the offer for sale to Phelps did not address inventive aspects of the '056 patent's new biopsy needle.

As support for its remaining contention -- that it had not developed the final design of the biopsy needle -- Bard points to Engstrom's testimony, as managing director of Radiplast, and correspondence between Radiplast,

American Pharmaseal, (one of Radiplast's potential distributors in the United States), and Alan Taylor (president of Hart Enterprises). Each of these letters was sent after the November 1984 offer for sale to Phelps, and each evidences continued testing of and proposed modifications to the second generation device and the new biopsy needles. *

Engstrom testified that American Pharmaseal's research and development laboratories conducted in-house testing. A technical report produced after this testing says that "testing [was] to insure functionality of the spring loaded activator, the Biopty(trade mark) device, and the needle before releasing them to the field trial." As a result of its testing, American Pharmaseal recommended: "increas[ing] the strength of the stylet handle design and add[ing] the buffing operation to cannula grinding process." Engstrom testified that this advice was "to, how do you say, make some changes on the plastic parts and also the -- what do you call that -- well, the, for some plastic parts broke actually, so we put some, a stopper in the second generation device to prevent, if that happened, to prevent the stylet to go further on." Engstrom testified that on American Pharmaseal's advice, Radiplast added a "stop" to the second generation device, after the offer to Phelps.

Engstrom also testified that Radiplast conducted field trials in December 1985, from which it learned that "there was a potential risk for this one snapping back and hurt the doctor's hand," and "many patients thought the noise of the instrument was very disturbing." As a result, Radiplast added "an automatic retraction, a spring, actually, which took this handle back," and "some damping things, you know, to reduce the noise of the instrument." After these field trials, Engstrom sent a letter to Hart Enterprises on January 15, 1985, which stated: "The needle should be changed according to our phone discussion, which means that the wings of the cannula hub should have the same length. Both should be as long as the shortest wing." A letter from Hart Enterprises to Engstrom on January 25, 1985, enclosed three drawings that show "[t]he cannula and stylet hub dimensions are identical to the drawings and prototype you had previously received, with the exception that the cannula hub wings are now [sym]metrical."

This evidence suggests that Radiplast modified the second generation device, by altering the strength of the stylet handle design, adding a buffing operation to the cannula grinding process, a stopper, automatic retraction via a spring, damping to reduce noise, and equal length symmetrical cannula hub wings as long as the shortest wing. However, Bard cannot avoid the on sale bar merely by showing improvements to the invention after its commercialization. *See, e.g., Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 98 F.3d 1318, 1324, 40 USPQ2d 1450, 1454-55 (Fed. Cir. 1996). These changes must be something more than obvious mechanical adjustments; they have to be inventive redesigns that are claimed by the '056 patent. While some of Radiplast's changes resulted in different possible embodiments of, or additions to, the new biopsy needle that is claimed by the '056 patent, none of the changes are claimed in the text of the '056 patent. Moreover, contrary to Bard's contentions, its evidence suggests at the very least that Radiplast had "reason to expect" in November 1984, that its needle "would work for its intended purpose upon completion," *Micro Chemical, Inc. v. Great Plains Chemical Co., Inc.*, 103 F.3d 1538, 1545, 41 USPQ2d 1238, 1244, and that Radiplast had more than a mere conception from which it was working towards development, *see UMC*, 816 F.2d at 657, 2 USPQ2d at 1472.

Because Bard's evidence shows nothing beyond unclaimed mechanical adjustments to the needle design claimed in the '056 patent after the November 1984 offer for sale of new biopsy needles, the jury had substantial evidence in support of its finding that the November 1984 offer for sale generated a statutory bar. *See, e.g., Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 112 F.3d 1163, 1167, 42 USPQ2d 1619, 1623 (Fed. Cir. 1997). A contrary view would attribute to the '056 patent additional limitations taken from later developed commercial embodiments.

Because the claimed invention had been completed, Engstrom's new biopsy needle design calls for an outcome different from *Robotic Vision*, 112 F.3d 1163, 42 USPQ2d 1619 (remanded for further fact finding on the completion date of a computer software program), *Micro Chemical*, 103 F.3d at 1544, 41 USPQ2d at 1243 (only a proposed configuration existed and the invention remained to be completed), and *Shatterproof Glass*, 758 F.2d at 623, 225

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USPQ at 640 (a reasonable jury could have found that "apparatus and method of the claims were not functional").

III. Policy Considerations

Other than the need for sufficient time to test the new biopsy needle design, which is not a policy consideration summoned by the November 1984 offer, Bard has not argued that there are policy considerations weighing against imposition of the on sale bar. Since the policies that underlie the bar focus on the inventor's attempts to exploit the invention, not whether a potential purchaser was made aware of or understood it, discussion of Phelps' actual knowledge of the details of the invention or the differences between generations of the biopsy gun is irrelevant. See, e.g., *Ferag*, 45 F.3d at 1568, 33 USPQ2d at 1516 ("We emphasize that this is an objective test, and that at its heart lies the inventor's attempt to commercialize the invention [T]he measure of the bar is what was offered, not the patentee's intent.") In light of the strong policy of preventing exploitation of the commercial value of an invention while deferring commencement of the statutory term, I would affirm the jury's application of the on sale bar.

Bryson, J., concurring in part and dissenting in part.

I concur in the portion of the court's opinion upholding the jury's verdict of non-infringement of the '308 patent. I also concur in the portions of the court's opinion reversing the district court's judgment that the '308 patent is invalid, and overturning the jury's verdict on the issue of fraud. Accordingly, I join parts II-V, VI.A-B, and VII of Judge Newman's opinion.

With respect to portions of the judgment relating to the '056 patent, I agree with Chief Judge Mayer that the '056 patent is invalid under the "on-sale bar" of 35 U.S.C. Section 102(b), although I take a somewhat different analytical path to that conclusion, as discussed below. Because I conclude that the '056 patent is invalid based on the on-sale bar, I do not reach the other grounds on which the jury found the '056 patent invalid.

Finally, Chief Judge Mayer and I agree that the jury verdict on M3's antitrust counterclaim must be affirmed. Because we do not uphold all of the grounds on which the jury found liability, however, we conclude that the jury may have improperly assessed damages on liability grounds that cannot stand. We therefore must remand for further proceedings to determine the proper amount of damages to be assessed on the antitrust counterclaim.

I

With respect to the on-sale bar, I believe that the June 1985 sale of 250 needles from Radiplast to Pharmaseal was sufficient to support the jury's verdict that the asserted claims of the '056 patent were rendered invalid by a sale more than one year before July 30, 1986, the effective filing date of the patent. It is undisputed that the needles sold in June 1985 embodied the invention of the '056 patent. Whether that sale was sufficient to invoke the on-sale bar turns on whether the sale falls within the "experimental purpose" exception to the on-sale bar.

A

In the summer of 1984, Radiplast began looking for a company "to distribute and promote the sales of [its] biopsy instruments in the United States." Pharmaseal, a potential distributor of the instruments, sent a telex to Radiplast stating that "before any formal purchasing plans can be made," it would have to conduct field trials "to determine the performance and specimen quality of your biopsy device and disposable needle." Pharmaseal sent letters to several hospitals in December 1984 inviting them to participate in a "field trial as a potential sales/distribution system for Radiplast devices."

Radiplast responded by telex on January 21, 1985, setting a price for the needles to be used in Pharmaseal's field trial and offering large-quantity discounts for batches of up to 50,000 needles. Radiplast's telex stated that "in order to be able to deliver both needles and instruments in beginning of March [1985], we need a [telex] order, preferably this week." It also stated that "we have to meet and discuss more in detail all things related with the marketing of our biopsy instrument in U.S." With respect to Pharmaseal's proposed field trial, Radiplast merely suggested that "if you would like [Dr. Lindgren, the inventor] to visit the hospitals performing the trial, in order to help them get started, he will be happy to help you."

Pharmaseal agreed to purchase the instruments and, on March 28, 1985, placed an order for 10 biopsy guns and 250 needles from Radiplast. The instruments were shipped in June 1985. It is undisputed that the June 1985 transaction constituted a sale and that the needles sold at that time embodied the invention of the '056 patent.

Pharmaseal conducted in-house testing of the devices in July 1985 before releasing the

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products to hospitals for the field trials. Following the in-house testing, Pharmaseal reported only minor problems and made minor manufacturing suggestions, such as recommending that Radiplast strengthen the stylet hub design and add a buffing operation to the cannula grinding process.

Although Bard contends that Dr. Lindgren attended some of the field trials and that Radiplast "was continually advised by Pharmaseal of [their] progress," Dr. Lindgren testified that he did not exercise any control over the tests, that he did not recall ever seeing the instrument used during a test, and that he did not receive or maintain any data from the tests. Bard appears to concede that the test results were not maintained in confidence, and it points to no evidence showing that the primary purpose of the tests was to ensure that the claimed features of the invention would operate as intended.

The field testing was performed at the behest of Pharmaseal, the purchaser, not Radiplast or the inventor. Pharmaseal "assumed primary responsibility" for the tests, while Radiplast merely "had an ongoing interest" in the progress of the trials and "was kept informed" of the progress of the field trials. During the field trials, Pharmaseal and Radiplast continued to discuss market potential, potential prices and volumes, and an instructional videotape to teach proper use of the instruments.

B

Bard argues that the jury verdict cannot stand because the in-house testing at Pharmaseal and the hospital field trials show that the sale was for experimental testing purposes. The so-called "experimental testing" exception to the on-sale bar applies only if commercial exploitation is "merely incidental to the primary purpose of experimentation to perfect the invention."

Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd., 731 F.2d 831, 839, 221 USPQ 561, 567 (Fed. Cir. 1984). In determining whether the inventor made the sale in question for

purposes of determining whether the invention would work for its intended purpose, a court must consider various factors, such as the amount of control the inventor exercised over the testing; the length of the test period; whether any payment was made; whether there was a secrecy obligation; whether progress records were kept; whether someone other than the inventor conducted the experiments; and the degree of commercial exploitation during the tests in relation to the purpose of the experimentation. *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564, 4 USPQ2d 1210, 1214 (Fed. Cir. 1987). Certain factors, such as the requirement that the inventor control the testing, that detailed progress records be kept, and that the purported testers know that testing is occurring, are critical to proving experimental purpose. *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120, 39 USPQ2d 1100, 1105 (Fed. Cir. 1996) ("if the inventor has no control over the alleged experiments, he is not experimenting"); see generally 2 Donald S. Chisum, *Patents* Section 6.02[7][c] (1998).

The evidence shows that Radiplast's primary purpose in making the sale to Pharmaseal was to market the patented invention through Pharmaseal, not to conduct tests to determine whether the claimed invention would work for its intended purpose. Neither the in-house testing at Pharmaseal nor the field trials at hospitals were conducted under the control or supervision of the inventor or Radiplast; instead, the tests were proposed, controlled, and monitored by Pharmaseal, the purchaser. Dr. Lindgren, the inventor, admitted at trial that he had no control over the field trials, that he did not maintain any test data, and that he did not recall receiving any test results. Radiplast was not aware of the identity of the patients in the field tests, the organs that were being biopsied, or the types of tests being performed; indeed, the patients were apparently not even informed that the biopsies were being conducted as part of a test. The hospitals participating in the field trials were told that the trials were intended as "a potential sales/distribution system for Radiplast devices." There is no evidence that any secrecy agreements were made with Pharmaseal, the hospitals, or any of the test participants. Finally, it is undisputed that Pharmaseal paid for the instruments and needles used in the tests. All of these factors point away from the conclusion that the sale was made for purposes of experimentation. See *Western Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 846, 226 USPQ 334, 339 (Fed. Cir. 1985) (no experimental use where evidence pointed to market testing rather than experimentation).

Significantly, at the time of the sale of 250 needles in June 1985, Radiplast had an open offer to sell large quantities of needles to Pharmaseal at bulk discount prices. The January 21, 1985, telex had offered batches of up to 50,000 needles for a specific price, and smaller quantities of 10,000 and 20,000 needles for somewhat higher prices. The offer of such large quantities of needles was clearly for commercial, rather than experimental,

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purposes, and by June 1985 it was clear that the needles that were being offered to Pharmaseal embodied the later-claimed invention. The bulk purchase offer provides further evidence that the June 1985 sale was not for experimental purposes. See *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1325, 40 USPQ2d 1450, 1455 (Fed. Cir. 1996) (Bryson, J., concurring) ("if the sale or offer in question embodies the invention for which a patent is later sought, a sale or offer to sell that is primarily for commercial purposes and that occurs more than one year before the application renders the invention unpatentable"). Thus, it appears that Radiplast was marketing the later-claimed needles commercially at least by late June 1985. Its willingness to sell smaller quantities of needles to Pharmaseal to use in its field tests was evidently an accommodation to Pharmaseal, which conducted its own tests before distributing

the needles to hospitals and doctors. The fact that Radiplast recognized that Pharmaseal intended to test the needles before distributing them in bulk, however, did not make Radiplast's offer and sale in 1985 any less commercial in nature.

The facts of this case are analogous to those in *U.S. Environmental Products, Inc. v. Westall*, 911 F.2d 713, 15 USPQ2d 1898 (Fed. Cir. 1990). In *Westall*, this court affirmed a district court's conclusion that a patent was invalidated by a sale more than one year before the filing date. That conclusion was based primarily on (1) the lack of written progress records and the failure to adhere to a testing schedule; (2) the inventor's failure to maintain control over the testing; and (3) promotion of the invention during the testing. *Id.* at 717-18. In this case, as in *Westall*, the evidence shows that neither the in-house tests at Pharmaseal nor the field tests at hospitals were under the control of the inventor or his company. There is little or no evidence of any written progress records; indeed, the inventor was apparently never provided with any test results. Finally, the communications between Radiplast and Pharmaseal throughout the purported testing period emphasized commercial sales and projections, not controlled experimentation.

Bard relies heavily on *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991), for the proposition that providing price estimates for future sales does not otherwise vitiate the experimental testing exception. In *Continental*, however, this court noted that "no sales were ever made"; there was a joint development project between two companies to develop the invention; and the project was "cloaked in confidentiality." 948 F.2d at 1269-70, 20 USPQ2d at 1750. Because the circumstances in *Continental* are so different from the circumstances in this case, *Continental* is of no help to Bard.

C

Bard also contends that the Pharmaseal sale cannot constitute a bar under 35 U.S.C. Section 102(b) because Radiplast did not make a profit on the transaction. The jury heard testimony, however, suggesting that Radiplast made a 60% profit on the Pharmaseal sale. Even ignoring any actual profit on the devices used in the field trials, it is clear that the Pharmaseal transaction was made primarily to develop a market for future sales, not primarily to test the claimed invention. At any rate, the failure to turn a profit is not determinative. "A patent owner may have created an on-sale bar despite losing money on a sale." *U.S. Envtl. Prods., Inc. v. Westall*, 911 F.2d 713, 717, 15 USPQ2d 1898, 1902 (Fed. Cir. 1990).

II

In support of its antitrust counterclaim, M3 presented three theories to the jury: (1) that Bard committed fraud in the procuring its patents (the *Walker Process* theory); (2) that Bard acted in bad faith in enforcing its patents (the "sham litigation" theory), and (3) that Bard modified its Biopsy gun for the purpose of preventing its competitors' needles from being used in that gun. Bard challenges the sufficiency of the evidence to support the jury's verdict on each of those three theories. The panel is unanimous in concluding that the evidence is insufficient to support liability on the *Walker Process* and "sham litigation" theories. Chief Judge Mayer and I agree, however, that there is sufficient evidence to affirm the jury's antitrust liability verdict based on Bard's gun modification program, for the reasons set forth below.

A

The jury considered evidence that Bard modified its Biopsy gun to prevent its competitors' non-infringing, flangeless needles from being used in Bard's guns. By special verdicts, the jury found that there was a relevant product market for replacement needles for fully automated

reusable biopsy guns, that Bard had monopoly power in that market, and that it had acquired or maintained its monopoly power in that market through restrictive or exclusionary conduct.

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[13] In order to prevail on its claim of an antitrust violation based on Bard's modification of its Biopty gun to prevent the use of competing replacement needles, M3 was required to prove that Bard made a change in its Biopty gun for predatory reasons, *i.e.*, for the purpose of injuring competitors in the replacement needle market, rather than for improving the operation of the gun. See *In re IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965, 1002 (N.D. Cal. 1979), *aff'd sub. nom. Transamerica Computer Co. v. International Bus. Mach. Corp.*, 698 F.2d 1377 (9th Cir. 1983); see generally 1 ABA, *Antitrust Law Developments* 286-87 (4th ed. 1997). Bard argues that the evidence showed that absent patent protection for Bard's devices, M3 could still compete in the relevant market. While the evidence of Bard's market power was in dispute, the jury specifically found that Bard enjoyed monopoly power in the market for replacement needles. The evidence was sufficient to support the jury's verdict on that point and also to support the jury's conclusion that Bard maintained its monopoly position by exclusionary conduct, to wit, modifying its patented gun in order to exclude competing replacement needles.

The dissent on this issue starts from the premise that the modification to Bard's Biopty gun was an "improvement" and argues from that premise that to hold Bard liable for the modification would have the "pernicious" effect of penalizing innovators for making improvements to their products. The dissent's premise, however, is contrary to the jury's verdict, which was supported by the evidence. Although Bard contended at trial that it modified its Biopty gun to make it easier to load and unload, there was substantial evidence that Bard's real reasons for modifying the gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of "copycat" needles. One internal Bard document showed that the gun modifications had no effect on gun or needle performance; another internal document showed that the use of non-Bard needles in the gun "could not possibly result in injury to either the patient or the physician." In view of that evidence, the jury could reasonably conclude that Bard's modifications to its guns constituted "restrictive or exclusionary conduct" in a market over which it had monopoly power.

The dissent also takes issue with the jury instructions, contending that they failed properly to frame a charge of predatory conduct that comports with established criteria of antitrust liability. Because Bard did not challenge the court's instructions, however, the legal sufficiency of the jury charge on the antitrust issues is not properly before us on appeal. To be entitled to relief based on asserted errors in the court's instructions to the jury, Bard was required to challenge those instructions in this court and demonstrate that it timely objected to those instructions in the district court. Bard did neither, but instead based its argument entirely on the sufficiency of the evidence. Because the evidence is sufficient to support the verdict on the gun modification theory of liability, the jury's liability verdict must stand. See *Mangren Research & Dev. v. National Chem. Co.*, 87 F.3d 937, 942 n.3 (7th Cir. 1996); *Composite Marine Propellers, Inc. v. Van Der Woude*, 962 F.2d 1263, 1265 (7th Cir. 1992).

B

While we affirm Bard's liability on the antitrust counterclaim, that does not necessarily mean that the jury's damage award of \$1.5 million can be sustained. M3 presented evidence of three

different markets (guns, guns and needles, and replacement needles) in which Bard allegedly caused antitrust injury, and the jury found Bard liable for injury in each market. The damages portion of the verdict, however, merely indicated a general award of \$1.5 million without attribution to a particular market or exclusionary practice.

M3's evidence concerning Bard's gun modification program was relevant only to the replacement needle market. Because we have concluded that the evidence concerning Bard's activities in the other two markets cannot support antitrust liability, the question arises as to whether the \$1.5 million damages award can be supported solely on the basis of the injury Bard's actions caused to M3 in the replacement needle market. That issue was not briefed on appeal, and the record, so far as we can ascertain, does not provide clear guidance as to the proper allocation of damages due to the injury suffered by M3 in the injury replacement needle market. Consequently, we vacate the antitrust damages award and remand to the district court to consider, after additional hearing or limited retrial, if necessary, the proper amount of damages attributable to Bard's gun modification program. See *MCI Communications Corp. v. American Tel. & Tel. Co.*, 708 F.2d 1081, 1166-67 (7th Cir. 1983).

Footnotes

Footnote 1. *C.R. Bard, Inc. v. M3 Sys., Inc.*, No. 93-CV-4788 (N.D. Ill. Oct. 2 & Dec. 20, 1995) (orders).

Footnote 2. *Section 102*. A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, . . .

Footnote 3. *Section 102* A person shall be entitled to a patent unless--

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, . . .

Footnote 4. This section is the dissenting opinion of Judge Newman. The court affirms the judgment of invalidity for violation of the on-sale bar, in separate opinions of Chief Judge Mayer and Judge Bryson.

Footnote 5. The three different views in the three opinions of this panel on the on-sale issue point up the need for a more certain law than today exists. Inventors and those who commercialize inventions should reasonably know when the on-sale bar starts to accrue, instead of awaiting litigation-borne *post hoc* judicial evaluations of the totality of the circumstances, varying with the nature of the invention, the nature of the customer contact, and the judicial weight given to the conflicting policy interests. I favor, as simple and fair, the bright line rule that for the Section 102(b) on-sale bar to accrue the invention must exist in commercial form when the offer of sale is made. This rule would implement the dominant policy of providing a one-year grace period for determining the performance of the product in the marketplace.

Footnote 6. The record provided us does not show any response from the PTO. Although Bard states that "the [PTO] determined that the transfers to American Pharmaseal [] were for primarily experimental purposes and therefore did not trigger the bar," the record citations do not relate to this statement.

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Footnote 7. In *Nobelpharma* the Federal Circuit held in banc that Federal Circuit law would thenceforth apply to determination of whether fraudulent conduct occurred in obtaining a patent, whereas determination of the other elements of the section 2 violation, viz. market power in the relevant market and illegal restraints on competition, since not unique to the patent right would continue to be governed by regional circuit law. 141 F.3d at 1067-68, 46 USPQ2d at 1104.

Footnote 8. M3 in its brief states that: "The Jury specifically found that BARD had 'actual knowledge' that M3 did not infringe its patents or that the patents were invalid. [A10096; 11-3 Paragraphs 6,11]." There is no specific finding in the verdict form of "actual knowledge." The cites to Paragraphs 6 & 11 are to the jury's finding of patent misuse, and the jury instructions at A10096 concern the duty of candor to the PTO. The source of the quoted "actual knowledge" is not given. Such misdirections are not helpful to the appellate tribunal; see also note 6, *supra*.
Footnote 9. The court has affirmed the district court's judgment of antitrust violation on this ground; see the separate opinion of Judge Bryson, joined by Chief Judge Mayer. This section contains the dissenting opinion of Judge Newman.

Footnote *. Reliance on Engstrom's trial testimony is inherently less reliable than contemporaneous documentary evidence. Cf. *TP Lab., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972, 220 USPQ 577, 583 (Fed. Cir. 1984) (inventor's expressions of "subjective intent . . . particularly after institution of litigation, is generally of minimal value").

- End of Case -

In re Rouffet (CA FC) 47 USPQ2d 1453

In re Rouffet ☐

U.S. Court of Appeals Federal Circuit ☐
47 USPQ2d 1453 ☐

Decided July 15, 1998 ☐
No. 97-1492

Headnotes

PATENTS

1. Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Claimed low orbit satellite communications system for mobile terminals, which addresses problem of minimizing "handover" of receiver from beam footprint of one transmitting satellite to that of another through use of multiple fan-shaped beams, is not prima facie obvious over combination of three prior art references, since critical reference that teaches use of fan-shaped beam to transmit from ground station to orbiting satellites does not specifically address handover minimization, and to extent it addresses handover problem at all, does so with orbit selection rather than beam shape, and since there is no reason one of ordinary skill in art, seeking to minimize handovers due to satellite motion, would have been motivated to combine this reference with remaining references in manner that would render claimed invention obvious.

2. Patentability/Validity -- Obviousness -- Person of ordinary skill in art (§ 115.0902)

Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Three possible sources for motivation to combine prior art references in manner that would render claimed invention obvious are nature of problem to be solved, teachings of prior art, and

knowledge of persons of ordinary skill in art; high level of skill in field of art cannot be relied upon to provide necessary motivation absent explanation of what specific understanding or technical principle, within knowledge one of ordinary skill in art, would have suggested combination, since, if such rote invocation could suffice to supply motivation to combine, more sophisticated scientific fields would rarely, if ever, experience patentable technical advance.

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3. Patentability/Validity – Obviousness – Person of ordinary skill in art (§ 115.0902)

Patentability/Validity – Obviousness – Combining references (§ 115.0905)

Claimed low orbit satellite communications system for mobile terminals is not prima facie obvious over combination of two prior art references, even though person possessing high level of skill characteristic of this field would know to account for differences between claimed invention and prior art combination, since high level of skill in art, without more, cannot supply required motivation to combine references, and does not overcome absence of any actual suggestion to combine; obviousness rejection will not be upheld, even where skill in art is high, absent specific identification of principle, known to one of ordinary skill, that suggests claimed combination.

Case History and Disposition:

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Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Denis Rouffet, Yannick Tanguy, and Frederic Berthault, serial no. 07/888,791, filed May 27, 1992. From decision upholding examiner's final rejection of application as obvious under 35 USC 103(a), applicants' appeal. Reversed.

Attorneys:

Richard C. Turner and Grant K. Rowan, of Sughrue, Mion, Zinn, Macpeak & Seas, Washington, D.C., for appellants.

David J. Ball Jr., associate solicitor, Nancy J. Linck, solicitor, Albin F. Drost, deputy

solicitor, Craig R. Kaufman, associate solicitor, and Scott A. Chambers, associate solicitor, U.S. Patent and Trademark Office, Arlington, Va., for appellee.

Judge:

Before Plager, circuit, judge, Archer, senior circuit judge, and Rader, circuit judge.

Opinion Text

Opinion By:

Rader, J.

Denis Rouffet, Yannick Tanguy, and Frederic Berthault (collectively, Rouffet) submitted application 07/888,791 (the application) on May 27, 1992. The Board of Patent Appeals and Interferences (the Board) affirmed final rejection of the application as obvious under 35 U.S.C. Section 103(a). See *Ex parte Rouffet*, No. 96-1553 (Bd. Pat. App. & Int. Apr. 16, 1997). Because the Board reversibly erred in identifying a motivation to combine the references, this court reverses.

I.

Satellites in a geosynchronous or geostationary orbit remain over the same point on the Earth's surface. Their constant position above the Earth's surface facilitates communications. These satellites project a number of beams to the Earth. Each beam transmits to its area of coverage, or footprint, on the Earth's surface. In order to provide complete coverage, adjacent footprints overlap slightly and therefore must use different frequencies to avoid interference. However, two or more non-overlapping footprints can use the same set of frequencies in order to use efficiently the limited radio spectrum. Figure 1 from the application shows the coverage of a portion of the Earth's surface provided by multiple cone shaped beams:



Frequency reuse techniques, however, have a limited ability to compensate for congestion in geostationary orbits. To alleviate the orbit congestion problem, new telecommunications systems use a network of satellites in low Earth orbit. When viewed from a fixed point on the Earth's surface, such satellites do not remain stationary but move overhead. A satellite's motion as it transmits a plurality of cone-shaped beams creates a new problem. The satellite's movement causes a receiver on the Earth's surface to move from the footprint of one beam into a second beam transmitted by the same satellite. Eventually, the satellite's motion causes the receiver to move from the footprint of a beam transmitted by one satellite into the footprint of a beam transmitted by a second satellite. Each switch from one footprint to another creates a "handover" event analogous to that which occurs when a traditional cellular phone travels from one cell to another. Handovers are undesirable because

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they can cause interruptions in signal transmission and reception. Rouffet's application discloses technology to reduce the number of handovers between beams transmitted by the same satellite. In particular, Rouffet eliminates handovers caused solely by

the satellite's motion. To accomplish this goal, Rouffet changes the shape of the beam transmitted by the satellite's antenna. Rouffet's satellites transmit fan-shaped beams. A fan beam has an elliptical footprint. Rouffet aligns the long axis of his beams parallel to the direction of the satellite's motion across the Earth's surface. By elongating the beam's footprint in the direction of satellite travel, Rouffet's invention ensures that a fixed point on the Earth's surface likely will remain within a single footprint until it is necessary to switch to another satellite. Because Rouffet's invention does not address handovers caused by the motion of the receiver across the Earth's surface, his arrangement reduces, but does not eliminate, handovers. Figure 3 from the application shows the footprints 12 from six beams aligned in the direction of satellite motion 15:



The application contains ten claims that stand or fall as a group. Claim 1 is representative: A low orbit satellite communications system for mobile terminals, wherein the communications antenna system of each satellite provides isoflux coverage made up of a plurality of fan beams that are elongate in the travel direction of the satellite.

The examiner initially rejected Rouffet's claims as unpatentable over U.S. Pat. No. 5,199,672 (King) in view of U.S. Pat. No. 4,872,015 (Rosen) and a conference report entitled "A Novel Non-Geostationary Satellite Communications System," *Conference Record*, International Conference on Communications, 1981 (Ruddy). On appeal to the Board, the examiner added an alternative ground for rejection, holding that the claims were obvious over U.S. Pat. No. 5,394,561 (Freeburg) in view of U.S. Pat. No. 5,170,485 (Levine).

On April 16, 1997, the Board issued its decision. Because Rouffet had specified that the claims would stand or fall as a group based on the patentability of claim 1, the Board limited its opinion to that claim. The Board unanimously determined that the examiner had properly rejected claim 1 as obvious over King in view of Rosen and Ruddy. The Board, on a split vote, also affirmed the rejection over Freeburg in view of Levine.

II

To reject claims in an application under section 103, an examiner must show an un rebutted *prima facie* case of obviousness. See *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). In the absence of a proper *prima facie* case of obviousness, an applicant who complies with the other statutory requirements is entitled to a patent. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of nonobviousness. See *id.*

While this court reviews the Board's determination in light of the entire record, an applicant may specifically challenge an obviousness rejection by showing that the Board reached an incorrect conclusion of obviousness or that the Board based its obviousness determination on incorrect factual predicates. This court reviews the ultimate determination of obviousness as a question of law. See *In re Lueders*, 111 F.3d 1569, 1571, 42 USPQ2d 1481, 1482 (Fed. Cir. 1997). The factual predicates underlying an obviousness determination include the scope and content of the prior art, the differences between the prior art and the claimed invention, and the level of ordinary skill in the art. See *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881, 45 USPQ2d 1977, 1981 (Fed. Cir. 1998). This court reviews the Board's factual findings for clear error. See *In re Zurko*, 142 F.3d 1447, 1449, 46 USPQ2d 1691, 1693 (Fed. Cir. 1998) (in banc); *Lueders*, 111 F.3d at 1571-72. "A finding is clearly erroneous

when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.' " *In re Graves* , 69 F.3d 1147, 1151, 36 USPQ2d

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1697, 1700 (Fed. Cir. 1995) (quoting *United States v. United States Gypsum Co.* , 333 U.S. 364, 395 [76 USPQ 430] (1948)).

The secondary considerations are also essential components of the obviousness determination. See *In re Emert* , 124 F.3d 1458, 1462, 44 USPQ2d 1149, 1153 (Fed. Cir. 1997) ("Without Emert providing rebuttal evidence, this *prima facie* case of obviousness must stand."). This objective evidence of nonobviousness includes copying, long felt but unsolved need, failure of others, see *Graham v. John Deere Co.* , 383 U.S. 1, 17-18 [148 USPQ 459] (1966), commercial success, see *In re Huang* , 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689-90 (Fed. Cir. 1996), unexpected results created by the claimed invention, unexpected properties of the claimed invention, see *In re Mayne* , 104 F.3d 1339, 1342, 41 USPQ2d 1451, 1454 (Fed. Cir. 1997); *In re Woodruff* , 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), licenses showing industry respect for the invention, see *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.* , 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997); *Pentec, Inc. v. Graphic Controls Corp.* , 776 F.2d 309, 316, 227 USPQ 766, 771 (Fed. Cir. 1985), and skepticism of skilled artisans before the invention, see *In re Dow Chem. Co.* , 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988). The Board must consider all of the applicant's evidence. See *Oetiker* , 977 F.2d at 1445 ("An observation by the Board that the examiner made a *prima facie* case is not improper, as long as the ultimate determination of patentability is made on the entire record."); *In re Piasecki* , 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). The court reviews factual conclusions drawn from this evidence for clear error. Whether the evidence presented suffices to rebut the *prima facie* case is part of the ultimate conclusion of obviousness and is therefore a question of law.

When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. See *In re Geiger* , 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). Although the suggestion to combine references may flow from the nature of the problem, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.* , 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), the suggestion more often comes from the teachings of the pertinent references, see *In re Sernaker* , 702 F.2d 989, 994, 217 USPQ 1, 5 (Fed. Cir. 1983), or from the ordinary knowledge of those skilled in the art that certain references are of special importance in a particular field, see *Pro-Mold* , 75 F.3d at 1573 (citing *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.* , 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985)). Therefore, "[w]hen determining the patentability of a claimed invention which combines two known elements, 'the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' " See *In re Beattie* , 974 F.2d 1309, 1311-12, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) (quoting *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.* , 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984)).

III

The parties agree that the five references asserted by the examiner are in the same field of endeavor as the invention. The parties also agree that the pertinent level of skill in the art -- design of satellite communications systems -- is high. On appeal, Rouffet asserts that the

examiner and the Board erred by improperly combining references to render the claimed invention obvious.

The Combination of King, Rosen, and Ruddy

The Board first affirmed the rejection of Rouffet's claims over a combination of King, Rosen, and Ruddy. King discloses a system for launching a plurality of satellites into low Earth orbits from a single launch vehicle. Rosen teaches a geostationary satellite that uses a plurality of fan beams with their long axes oriented in an east-west direction to communicate with mobile and fixed terminals on the Earth.

The final, and most important, reference in this combination is Ruddy. Ruddy describes a television broadcast system that uses a series of satellites to retransmit signals sent from a ground station over a wide area. Rather than using a geostationary orbit, Ruddy teaches the use of a series of satellites in Molniya orbits. A satellite in a Molniya orbit always follows the same path through the sky when viewed from a fixed point on the ground. Viewed from the Earth, the orbital path includes a narrow, elliptical apogee loop. In order to transmit to these moving satellites from a ground station, Ruddy uses a fan beam with a long axis aligned with the long axis of the orbit's apogee loop. This alignment places the entire apogee loop within the footprint of the beam and eliminates the need for the ground station's antenna to track the satellite's motion around the apogee loop. Ruddy further teaches orbit parameters

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and spacing of multiple satellites to ensure that a satellite is always in the loop to receive and rebroadcast signals from the Earth station.

King and Rosen together teach the use of a network of satellites in low Earth orbit. Thus, Ruddy becomes the piece of the prior art mosaic that shows, in the reading of the Board, the use of "a plurality of fan beams that are elongate in the travel direction of the satellite." Ruddy, however, is different from the claimed invention in several respects. Specifically, the application claims the projection of multiple elliptical fan-shaped footprints from the satellite to the ground. *See* Claim 1, *supra*, *see also* Application at 6, lines 9-11 ("In addition, in this system, the geometrical shape of the beams 12 is changed: instead of being circular they are now elongate ellipses."). The application's written description further teaches that the invention's fan-shaped satellite beams will minimize handovers. *See id.* at lines 11-16 ("This considerably increases call durations between handovers.").

In contrast, Ruddy teaches that a ground station may use a single fan-shaped beam to transmit to a satellite in a unique Molniya orbit. The ground station transmits a beam into which a series of satellites in Molniya orbits will successively enter. At least two differences are evident: the application teaches projection of multiple beams from a satellite to the Earth, while Ruddy teaches projection of a single beam from the Earth to satellites. Moreover to the extent Ruddy contains a teaching about handovers, its teachings focus on use of the unique Molniya orbit to ensure that a satellite always falls within the beam transmitted by the ground station.

These differences suggest some difficulty in showing a *prima facie* case of obviousness. The Board, however, specifically found that artisans of ordinary skill in this field of art would know to shift the frame of reference from a ground station following a satellite to a satellite transmitting to the ground. According proper deference to the Board's finding of a lofty skill level for ordinary artisans in this field, this court discerns no clear error in the Board's conclusion that these differences would not preclude a finding of obviousness. While Ruddy does not expressly teach alignment of the fan beam with the apparent direction of the satellite's

motion, this court perceives no clear error in the Board's determination that Ruddy would suggest such an alignment to one of skill in this art. Therefore, the Board did not err in finding that the combination of King, Rosen, and Ruddy contains all of the elements claimed in Rouffet's application.

[1] However, the Board reversibly erred in determining that one of skill in the art would have been motivated to combine these references in a manner that rendered the claimed invention obvious. Indeed, the Board did not identify any motivation to choose these references for combination. Ruddy does not specifically address handover minimization. To the extent that Ruddy at all addresses handovers due to satellite motion, it addresses this subject through the selection of orbital parameters. Ruddy does not teach the choice of a particular shape and alignment of the beam projected by the satellite. Thus Ruddy addresses the handover problem with an orbit selection, not a beam shape. The Board provides no reasons that one of ordinary skill in this art, seeking to minimize handovers due to satellite motion, would combine Ruddy with Rosen and King in a manner that would render the claimed invention obvious. Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. See 35 U.S.C. Section 103(a). This legal construct is akin to the "reasonable person" used as a reference in negligence determinations. The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan. See *In re Carlson*, 983 F.2d 1032, 1038, 25 USPQ2d 1207, 1211 (Fed. Cir. 1993).

As this court has stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996). To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to

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show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

[2] This court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In this case, the Board relied upon none of these. Rather, just as it relied on the high level of skill in the art to overcome the differences between the claimed invention and the selected elements in the references, it relied upon the high level of skill in the art to provide the necessary motivation. The Board did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art

would have suggested the combination. Instead, the Board merely invoked the high level of skill in the art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

Because the Board did not explain the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no knowledge of Rouffet's invention to make the combination, this court infers that the examiner selected these references with the assistance of hindsight. This court forbids the use of hindsight in the selection of references that comprise the case of obviousness. See *In re Gorman*, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). Lacking a motivation to combine references, the Board did not show a proper *prima facie* case of obviousness. This court reverses the rejection over the combination of King, Rosen, and Ruddy.

The Combination of Freeburg and Levine

Freeburg teaches a cellular radiotelephone system based on a constellation of low Earth orbit satellites that use conical beams to transmit from the satellite to both fixed and mobile Earth stations. Levine teaches an Earth-based cellular radio system that uses fan beams broadcast from antenna towers. Levine's elliptical footprints are aligned with the road grid. To increase the capacity of traditional ground-based systems through frequency reuse techniques, Levine teaches the use of antennas that broadcast signals with smaller footprints than the prior art system. Thus, Levine actually increases the number of overlap regions between cells and, hence, the number of potential handovers. Figure 1 of the Levine patent illustrates its alignment of beam footprints:



As a mobile unit (e.g., a driver using a car phone) moves through a succession of overlapping zones, Levine uses selection algorithms to determine which of the cells is aligned with the travel direction of the mobile unit. These algorithms then select this cell for use while continually monitoring intersecting cells in the event that the mobile unit changes direction. Once again, this court notes significant differences between the teachings of the application and the Levine-Freeburg combination. The critical Levine reference again involves a beam from an Earth station without any reference to the "travel direction of [a] satellite." Moreover, Levine actually multiplies the number of potential handovers and then uses software to sort out the necessary handovers from the unnecessary. However, the Board explains the reasons that one possessing the lofty skills characteristic of this field would know to account for the differences between the claimed invention and the prior art combination. This court discerns no clear error in that reliance on the considerable skills in this field.

[3] This court does, however, discern reversible error in the Board's identification of a motivation to combine Levine and Freeburg. In determining that one of skill in the art would have had motivation to combine Levine and Freeburg, the Board noted that "[t]he level of skill in the art is very high." As noted before, this observation alone cannot supply the required

suggestion to combine these references. The Board posits that the high level of skill in the art overcomes the absence of any actual suggestion that one could select part of the teachings of Levine for combination with the satellite system disclosed by Freeburg.

As noted above, the suggestion to combine requirement is a safeguard against the use of hindsight combinations to negate patentability. While the skill level is a component of the inquiry for a suggestion to combine, a lofty level of skill alone does not suffice to supply a motivation to combine. Otherwise a high level of ordinary skill in an art field would almost always preclude patentable inventions. As this court has often noted, invention itself is the process of combining prior art in a nonobvious manner. *See, e.g., Richdel*, 714 F.2d at 1579; *Environmental Designs*, 713 F.2d at 698. Therefore, even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. *Cf. Gechter v. Davidson*, 116 F.3d 1454, 43 USPQ2d 1030 (Fed. Cir. 1997) (explaining that the Board's opinion must describe the basis for its decision). In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

The Board's naked invocation of skill in the art to supply a suggestion to combine the references cited in this case is therefore clearly erroneous. Absent any proper motivation to combine part of Levine's teachings with Freeburg's satellite system, the rejection of Rouffet's claim over these references was improper and is reversed.

IV

The Board reversibly erred in determining that there was a motivation to combine either the teachings of King, Rosen, and Ruddy or of Freeburg and Levine in a manner that would render the claimed invention obvious. Because this predicate was missing in each case, the Board did not properly show that these references render the claimed invention obvious. Therefore this court reverses the Board's decision upholding the rejection of Rouffet's claims. In light of this disposition, Rouffet's pending motion to remand the case to the Board for further consideration is denied as moot.

COSTS

Each party shall bear its own costs.

REVERSED .

- End of Case -

In re Fritch (CA FC) 23 USPQ2d 1780

In re Fritch

U.S. Court of Appeals Federal Circuit
23 USPQ2d 1780

Decided August 11, 1992
No. 91-1318

Headnotes

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure -- Judicial review -- Standard of review -- Patents (§ 410.4607.09)

Obviousness determination is based on underlying factual inquiries concerning claimed invention and prior art, which are reviewed for clear error on appeal, but ultimate conclusion of obviousness is reviewed as matter of law.

PATENTS

2. Patent construction -- Claims -- Broad or narrow (§ 125.1303)

Prior art patent for grass edging and watering device cannot be held to teach that device is flexible and conformable to ground in its entirety, since base portion of device includes prominent anchoring leg which would inhibit longitudinal flexibility, and since patent's express teaching that trench is necessary to install device in harder ground shows that it is not freely conformable thereto.

3. Patentability/Validity -- Obviousness -- Relevant prior art -- Particular inventions (§ 115.0903.03)

Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Claims for landscape edging device are not prima facie obvious in view of combined teachings of two prior patents, since primary reference does not suggest overall flexibility and landscape retention function of claimed device, and since secondary reference does not, merely by virtue of flexibility of device described therein, suggest extensive modifications which would bring primary reference into conformity with application claims.

4. Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Mere fact that prior art may be modified to reflect features of claimed invention does not make modification, and hence claimed invention, obvious unless desirability of such modification is suggested by prior art; claimed invention cannot be used as instruction manual or "template" to piece together teachings of prior art so that claimed invention is rendered obvious.

Case History and Disposition:

Page 1780

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of John R. Fritch (serial no. 06/838,721, landscape apparatus and method). From decision upholding rejection of application claims 1-7, 9-24, 29 and 30, applicant appeals. Reversed.

Attorneys:

Charles L. Gholz, of Oblon, Spivak, McClelland, Maier & Neustadt, Arlington, Va. (John R. Fritch, Corpus Christi, Texas, on brief), for appellant.

Jameson Lee, associate solicitor (Fred E. McKelvey, solicitor, with him on brief; Richard E. Schafer, of counsel), for appellee.

Judge:

Before Smith, senior circuit judge, and Plager and Rader, circuit judges.

Opinion Text

Opinion By:

Smith, J.

John R. Fritch (Fritch) appeals the 27 February 1991 decision of the Patent and Trademark Office Board of Patent Appeals and Interferences (Board) affirming-in-part the Examiner's final rejection of the remaining claims in Fritch's application entitled Landscape Edging Apparatus and Method. 1 The Examiner concluded that Fritch's invention would have been obvious to one of ordinary skill in the art and was therefore unpatentable under 35 U.S.C. Section 103. The Board, except for allowing claim 28, agreed. The Board's decision is reversed.

Issue

The issue is whether the Board erred in affirming the Examiner's determination that the prior art references of Wilson and Hendrix rendered

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the subject matter of Fritch's independent claims 1, 13, 24, and 29 obvious to one of ordinary skill in the art.

Background

In his final rejection, the Examiner rejected claims 1-24 and 27-30 of Fritch's application as unpatentable for obviousness under 35 U.S.C. Section 103. Fritch appealed the final rejection to the Board. The Board affirmed the rejection as to claims 1-24, 29 and 30, entered a new ground of rejection for claim 27, and reversed as to claim 28. The Board agreed with the Examiner that the teachings of the Wilson and Hendrix patents rendered the subject matter of independent claims 1, 13, 24, and 29 obvious to one of ordinary skill in the art. Fritch does not appeal the Board's disposition as to claims 27 and 28, and at oral argument withdrew the appeal as to claim 8. The claims remaining in this appeal are 1-7, 9-24, 29 and 30.

The Fritch Invention

The invention claimed by Fritch involves a landscape edging device which includes a planar base portion and an upwardly extending retainer portion. The base portion is elongate, thin, flexible and has a planar bottom surface conformable to a varying slope ground surface. One longitudinal edge of the base portion serves as a mowing strip and the other serves as a retaining flange for landscape fill. The upwardly extending retainer portion is integrally connected (e.g., fused) to the base portion and defines a longitudinally extending enclosed space. The Fritch invention is intended to be used as a retainer for landscape fill in order to separate unmowable landscape fill from the mowable lawn. It may also be used to secure a landscaping sheet to the ground, or to function as guards at the base of a fence. Independent claims 1 and 13 on appeal are representative of the subject matter claimed:

1. A landscape edging strip formed in its entirety of a thin gauge, flexible material and

conformable to a ground surface of varying slope, comprising a continuous elongate, thin gauge, flexible base portion having a planar bottom surface conformable to said varying slope ground surface; a thin gauge, elongate retainer portion integral with said base portion and extending upwardly therefrom and transversely thereover to overlie a portion of said base portion; all of said retainer portion defining a longitudinally extending enclosed space; said retainer portion being integrally connected to said base portion adjacent one longitudinal edge of said base portion to define a mowing strip adjacent the other longitudinal edge of said base portion.

* * * * *

13. A landscape edging strip formed in its entirety from thin gauge, flexible material and conformable to a ground surface of varying slope, comprising a continuous elongate, thin gauge, flexible base portion having a planar bottom surface conformable to said varying slope ground surface; a thin gauge, elongate retainer portion integral with said base portion and extending upwardly therefrom and transversely thereover to overlie a portion of said base portion; all of said retainer portion defining a longitudinally extending enclosed space; said retainer portion being integrally connected to said base portion at a transverse location between the longitudinal edges of said base portion, thereby defining a longitudinally extending retaining flange on one side of said retainer portion and a mowing strip on the other side of said retainer portion.

* * * * * The critical language in Fritch's independent claims is that the device is to be, in its entirety, both flexible and "conformable to a ground surface of varying slope". These limitations, although located in the claims' preambles, "are necessary to give meaning to the claim [s] and properly define the invention". 2 Figure 1 from Fritch's drawings is reproduced below:

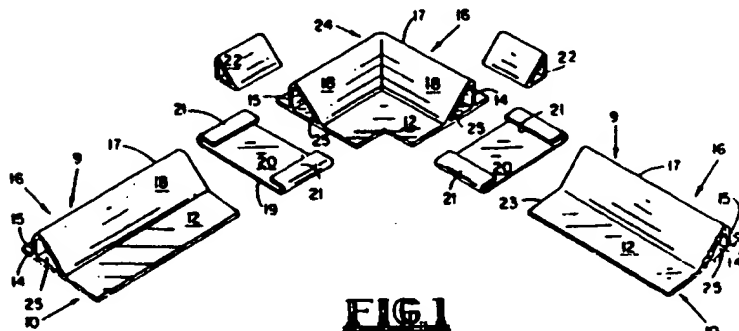


FIG. 1

The Prior Art. The Wilson Patent

The Wilson patent relied upon by the Examiner and the Board is entitled "Grass Edging and Watering Device". 3 The embodiment of the Wilson device includes a substantially flat mowing strip extending horizontally from a longitudinally extending body portion. Opposite the mowing strip is a scored flange which may be broken off when not needed or wanted. Between the mowing strip and the flange, and extending vertically from the body portion is an anchoring leg. Located above the anchoring leg is the body portion which contains a water conduit and sprinkler head assembly. The device is intended to be used adjacent to the borders of walks and plant beds. Figures 1 and 4 from Wilson's drawings are reproduced below:

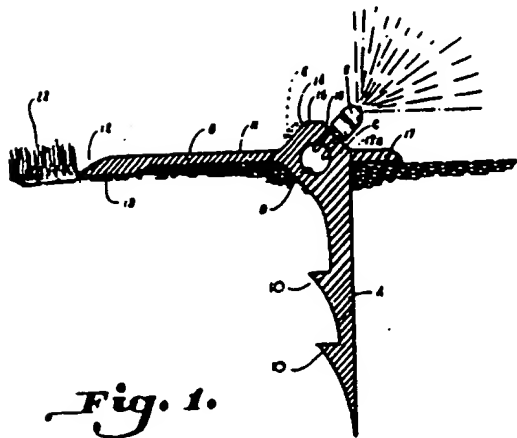


Fig. 1.

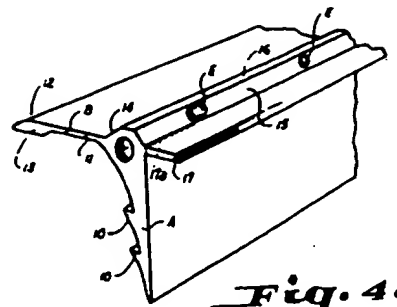


Fig. 4.

b. The Hendrix Patent

The Hendrix patent is entitled "Loose Material Retainer Strip". 4 The Solicitor chose not to discuss the Hendrix reference in his brief, stating that the Board had deemed Hendrix unnecessary to its decision. The Solicitor overstates the Board's position. The Board based its decision upon "a collective evaluation of the Wilson and Hendrix patents". We include Hendrix in our discussion because it did play a role in the rejection of Fritch's independent claims.

The Hendrix device is composed of elongated, flexible strips having substantially C-shaped cross-section. The bottom lip of the device is to be wider than the top lip in order to facilitate fastening the device to the ground. The device will fit most gentle contours, and the top lip will yield laterally to build-up of gravel until the gravel can be redistributed. The concave portion of the strip is installed such that it faces the material to be retained in place. Hendrix contemplates that the retainer will be used in retaining gravel in driveways, lining flower beds, or on the shoulders of asphalt or concrete highways. Figure 1 of Hendrix's drawings is reproduced below:

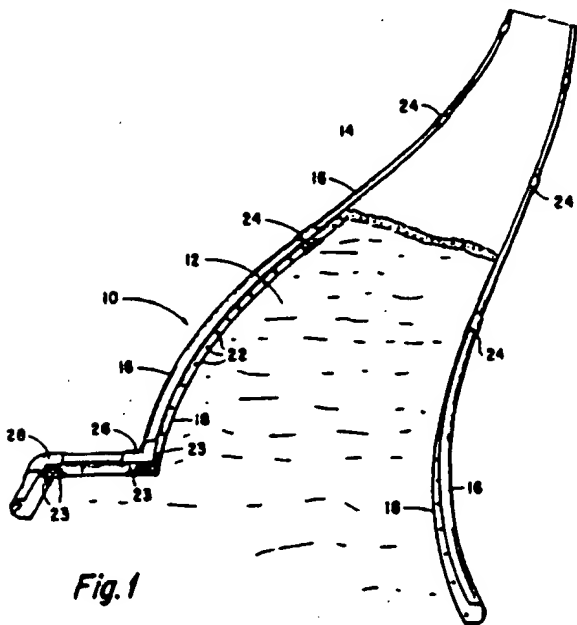


Fig. 1

Standard of Review

[1] "[O]bviousness is a question of law to be determined from the facts."⁵ The obviousness determination "is based upon underlying factual inquiries concerning the claimed invention and the prior art" which are reviewed for clear error.⁶ However, it is the ultimate conclusion of obviousness which the Federal Circuit reviews as a matter of law.⁷

Teachings of Wilson

Fritch takes exception to the Examiner's findings of fact related to the teachings of the Wilson patent. The Examiner's rejection and the Board's opinion rely heavily on the use of Wilson in view of other references to declare the Fritch invention obvious. The Board states that it agrees with the Examiner's finding of fact regarding the teachings of Wilson. In the Examiner's answer, which the Board quotes, the Wilson device is described as follows:

Wilson discloses a landscaping edging strip comprising a relatively thin gauge, elongated flexible base portion including a mower strip B having a planar bottom surface conformable to a varying slope surface.

The Board states that the Wilson reference presents "substantial evidence that Wilson is both thin and flexible." The Board regards the Wilson device as teaching that it is flexible and conformable in its entirety. This finding demonstrates clear error.

[2] It is well settled that a prior art reference is relevant for all that it teaches to those of ordinary skill in the art.⁸ The base portion of Wilson is not planar in its entirety, as the Board's opinion suggests, but also includes a prominent anchoring leg to secure the device to the ground. The anchoring leg, which runs the length of the Wilson device, would inhibit longitudinal flexibility of the Wilson device. Indeed, Wilson expressly contemplates flexibility and conformability *only* in the mower strip. Wilson states that its mower strip may be lifted in order to pack dirt thereunder for the purpose of securing the device to the ground. Fritch, on the other hand, is claimed to be flexible in its entirety.

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The Board's holding that Wilson is flexible in its entirety is based upon a misapprehension of the scope of Wilson's teachings.

Second, Wilson's anchoring leg prohibits conformability to the ground surface in the manner claimed by Fritch. The Examiner's description of Wilson as having a "planar bottom surface conformable to a varying slope surface" is applicable *only* in reference to the mower strip. This description, however, ignores the anchor leg and the fact that it must be placed *into* the ground. Wilson expressly teaches that the anchoring leg may be pushed into soft soils, but in harder terrain a trench is needed in order to place the Wilson sprinkler system. In order to install the Wilson apparatus, the ground surface must be altered to conform to the device rather than, as the Solicitor contends, that Wilson is freely conformable to the ground. Fritch, on the other hand, does not require such extensive alteration of the ground surface in order to install the device.

Prima Facie Obviousness

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.⁹ "[The Examiner] can

satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." 10 The patent applicant may then attack the Examiner's prima facie determination as improperly made out, or the applicant may present objective evidence tending to support a conclusion of nonobviousness." 11

Fritch has attacked the Board's finding that the Examiner established that Fritch's claimed invention was prima facie obvious in view of the teachings of the prior art. The Board states that "a collective evaluation of the Wilson and the Hendrix patents would have rendered the subject matter of independent claims 1, 13, 24, and 29 obvious to one of ordinary skill." Fritch maintains that there is no teaching, suggestion, or incentive in the prior art to modify or to combine the teachings of the prior art in the manner suggested by the Examiner. We agree.

[3] Wilson teaches a grass edging and watering device which includes an anchoring leg for securing the device to the ground. Wilson contemplates that a trench will need to be dug in order to allow the anchoring leg to be placed into the ground if the condition of the soil requires it. This anchoring leg prohibits flexibility and conformability over the length of Wilson. Any flexibility or conformability in Wilson, which the Board states extends to the entire device, is limited to the mower strip. It is only the mower strip that is mentioned as being flexible in order to aid installation. Hendrix has been cited for its teaching of a flexible retainer strip that is able to conform to the ground surface.

Wilson addresses the problems of arresting growth of grass between areas and watering plants without wetting sidewalks. Wilson lacks any suggestion or incentive to use its water conduit as a landscape retainer since this would arguably result in clogged sprinkler heads. 12 Wilson also teaches that its mower strip is flexible in order to allow dirt to be packed thereunder. There is no suggestion in Wilson to extend that flexibility to the entire device. Wilson also lacks any teaching or suggestion that one should remove the anchoring leg. Hendrix does not, simply by virtue of its flexible nature, suggest these extensive changes which the Board states are obvious. Neither Wilson nor Hendrix, alone or in combination, provide any incentive to combine the teachings of the prior art in the manner maintained by the Board.

[4] "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." 13 Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested

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the desirability of the modification. 14 Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board.

Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. 15 This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." 16

Conclusion

The decision of the Board affirming the Examiner's rejection of independent claims 1, 13, 24,

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and 29 of Fritch's application as unpatentable over the prior art under 35 U.S.C. Section 103 is reversed. Since dependent claims are nonobvious if the independent claims from which they depend are nonobvious, the Board's affirmance of the rejection of dependent claims 2-7, 9-12, 14-23, and 30 is also reversed.¹⁷

REVERSED

Footnotes

Footnote 1. Serial No. 06/838,721.

Footnote 2. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 896, 221 USPQ 669, 675 (Fed. Cir. 1984).

Footnote 3. U.S. Patent No. 3,485,449.

Footnote 4. U.S. Patent No. 4,349,596.

Footnote 5. *In re De Blauwe*, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984).

Footnote 6. *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir. 1990).

Footnote 7. *In re De Blauwe*, 736 F.2d at 703, 222 USPQ at 195.

Footnote 8. *Beckman Instruments Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989).

Footnote 9. *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984).

Footnote 10. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lahu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)).

Footnote 11. *In re Heldt*, 433 F.2d 808, 811, 167 USPQ 676, 678 (CCPA 1970).

Footnote 12. This court has previously found a proposed modification inappropriate for an obviousness inquiry when the modification rendered the prior art reference inoperable for its intended purpose. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

Footnote 13. *ACS Hosp. Systems, Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).

Footnote 14. *In re Gordon*, 733 F.2d at 902, 221 USPQ at 1127.

Footnote 15. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). See also *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

Footnote 16. *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600.

Footnote 17. *In re Fine*, 837 F.2d at 1076, 5 USPQ2d at 1600 (citing *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987)). See also *In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983) (when argued together, dependent claims stand or fall with the independent claims from which they depend).

- End of Case -

In re Fine (CA FC) 5 USPQ2d 1596

In re Fine

U.S. Court of Appeals Federal Circuit
5 USPQ2d 1596

Decided January 26, 1988
No. 87-1319

Headnotes

PATENTS

1. Patentability/Validity -- Obviousness -- Evidence of (§ 115.0903)

Patent and Trademark Office improperly rejected claimed invention for obviousness since nothing in cited references, either alone or in combination, suggests or teaches claimed invention, since there is consequently no support for PTO's conclusion that substitution of one type of detector for another in prior art system, resulting in claimed invention, would have been obvious, and since PTO therefore failed to satisfy its burden of establishing prima facie case of obviousness by showing some objective teaching or generally available knowledge that would lead one skilled in art to combine teachings of existing references.

2. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

Obviousness is tested by what combined teachings of prior art references would have suggested to those of ordinary skill in art, not by whether particular combination of elements from such references might have been "obvious to try."

3. Patentability/Validity -- Obviousness -- Evidence of (§ 115.0903)

Patent and Trademark Office erred, in rejecting as obvious system for detecting and measuring minute quantities of nitrogen compounds, by failing to recognize that appealed claims can be

distinguished over combination of prior art references, in view of evidence demonstrating that prior art does not teach claimed temperature range, despite some overlap of preferred temperature ranges for claimed invention and prior art, since purposes of preferred temperature ranges are different and overlap is mere happenstance.

4. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

Dependent claims are non-obvious under 35 USC 103 if claims from which they depend are non-obvious.

Case History and Disposition:

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Appeal from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

Application for patent by David H. Fine, Serial No. 512,374. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicant appeals. Reversed; Smith, circuit judge, dissenting with opinion.

Attorneys:

Morris Relson and Darby & Darby, New York, N.Y., (Beverly B. Goodwin with them on the brief) for appellant.

Lee E. Barrett, associate solicitor, Arlington, Va., (Joseph F. Nakamura, solicitor, and Fred E. McKelvey, deputy solicitor, with him on the brief) for appellee.

Judge:

Before Friedman, Smith, and Mayer, circuit judges.

Opinion Text

Opinion By:

Mayer, J.

David H. Fine appeals from a decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (Board) affirming the rejection of certain claims of

his application, Serial No. 512,374, and concluding that his invention would have been obvious to one of ordinary skill in the art and was therefore unpatentable under 35 U.S.C. §103. We reverse.

Background

A. The Invention .

The invention claimed is a system for detecting and measuring minute quantities of nitrogen compounds. According to Fine, the system has the ability to detect the presence of nitrogen compounds in quantities as minute as one part in one billion, and is an effective means to detect drugs and explosives, which emanate nitrogen compound vapors even when they are concealed in luggage and closed containers.

The claimed invention has three major components: (1) a gas chromatograph which separates a gaseous sample into its constituent parts; (2) a converter which converts the nitrogen compound effluent output of the chromatograph into nitric oxide in a hot, oxygen-rich environment; and (3) a detector for measuring the level of nitric oxide. The claimed invention's sensitivity is achieved by combining nitric oxide with ozone to produce nitrogen dioxide which concurrently causes a detectable luminescence. The luminescence, which is measured by a visual detector, shows the level of nitric oxide which in turn is a measure of nitrogen compounds found in the sample.

The appealed claims were rejected by the Patent and Trademark Office (PTO) under 35 U.S.C. §103. Claims 60, 63, 77 and 80 were rejected as unpatentable over Eads, Patent No. 3,650,696 (Eads) in view of Warnick, et al., Patent No. 3,746,513 (Warnick). Claims 62, 68, 69, 79, 85 and 86 were rejected as unpatentable over Eads and Warnick in view of Glass, et al., Patent No. 3,207,585 (Glass).

B. The Prior Art .

1. Eads Patent .

Eads discloses a method for separating, identifying and quantitatively monitoring sulfur compounds. The Eads system is used primarily in "air pollution control work in the scientific characterization of odors from sulfur compounds."

The problem addressed by Eads is the tendency of sulfur compounds "to adhere to or react with the surface materials of the sampling and analytical equipment, and/or react with the liquid or gaseous materials in the equipment." Because of this, the accuracy

Page 1598

of measurement is impaired. To solve the problem, the Eads system collects an air sample containing sulfur compounds in a sulfur-free methanol solution. The liquid is inserted into a gas chromatograph which separates the various sulfur compounds. The compounds are next sent through a pyrolysis furnace where they are oxidized to form sulfur dioxide. Finally, the sulfur dioxide passes through a measuring device called a microcoulometer which uses titration cells to calculate the concentration of sulfur compounds in the sample.

2. Warnick Patent .

Warnick is directed to a means for detecting the quantity of pollutants in the atmosphere. By measuring the chemiluminescence of the reaction between nitric oxide and ozone, the Warnick device can detect the concentration of nitric oxide in a sample gaseous mixture.

Warnick calls for "continuously flowing" a sample gaseous mixture and a reactant containing ozone into a reaction chamber. The chemiluminescence from the resulting reaction is transmitted through a light-transmitting element to produce continuous readouts of the total amount of nitric oxide present in the sample.

3. Glass Patent.

The invention disclosed in Glass is a device for "completely burning a measured amount of a substance and analyzing the combustion products." A fixed amount of a liquid petroleum sample and oxygen are supplied to a flame. The flame is then spark-ignited, causing the sample to burn. The resulting combustion products are then collected and measured, and from this measurement the hydrogen concentration in the sample is computed.

C. The Rejection .

The Examiner rejected claims 60, 63, 77 and 80 because "substitution of the [nitric oxide] detector of Warnick for the sulfur detector of Eads would be an obvious consideration if interested in nitrogen compounds, and would yield the claimed invention." He further asserted that "Eads teaches the [claimed] combination of chromatograph, combustion, and detection, in that order. . . . Substitution of detectors to measure any component of interest is well within the skill of the art." In rejecting claims 62, 68, 69, 79, 85 and 86, the Examiner said, "Glass et al. teach a flame conversion means followed by a detector, and substitution of the flame conversion means of Glass et al. for the furnace of Eads would be an obvious equivalent and would yield the claimed invention." The Board affirmed the Examiner's rejection.

Discussion

A. Standard of Review .

Obviousness under 35 U.S.C. §103 is " 'a legal conclusion based on factual evidence.' " *Stratoflex, Inc. v. Aeroquip Corp.* , 713 F.2d 1530, F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983) (quoting *Stevenson v. Int'l Trade Comm'n* , 612 F.2d 546, 549, 204 USPQ 276, 279 (CCPA 1979)). Therefore, an obviousness determination is not reviewed under the clearly erroneous standard applicable to fact findings, *Raytheon Co. v. Roper Corp.* , 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983); it is "reviewed for correctness or error as a matter of law." *In re De Blauwe* , 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984).

To reach a proper conclusion under §103, the decisionmaker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In light of *all* the evidence, the decisionmaker must then determine whether . . . the claimed invention as a whole would have been obvious at *that* time to *that* person. 35 U.S.C. §103. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts.

Panduit Corp. v. Dennison Mfg. Co. , 810 F.2d 1561, 1566, 1 USPQ2d 1593, 1595-96 (Fed. Cir. 1987).

B. Prima Facie Obviousness .

Fine says the PTO has not established a *prima facie* case of obviousness. He contends the references applied by the Board and Examiner were improperly combined, using hindsight reconstruction, without evidence to support the combination and in the face of contrary teachings in the prior art. He argues that the appealed claims were rejected because the PTO thought it would have been "obvious to try" the claimed invention, an unacceptable basis for rejection.

[1] We agree. The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. See *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-87 (Fed. Cir. 1984). It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984); see also *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*,

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776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). This it has not done. The Board points to nothing in the cited references, either alone or in combination, suggesting or teaching Fine's invention.

The primary basis for the Board's affirmance of the Examiner's rejection was that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. The Board reiterated the Examiner's bald assertion that "substitution of one type of detector for another in the system of Eads would have been within the skill of the art," but neither of them offered any support for or explanation of this conclusion.

Eads is limited to the analysis of sulfur compounds. The particular problem addressed there is the difficulty of obtaining precise measurements of sulfur compounds because of the tendency of sulfur dioxide to adhere to or react with the sampling analytic equipment or the liquid or gaseous materials in the equipment. It solves this problem by suggesting that the gaseous sample containing sulfur compounds be absorbed into sulfur-free methanol and then inserted into a gas chromatograph to separate the sulfur compounds.

There is no suggestion in Eads, which focuses on the unique difficulties inherent in the measurement of sulfur, to use that arrangement to detect nitrogen compounds. In fact, Eads says that the presence of nitrogen is undesirable because the concentration of the titration cell components in the sulfur detector is adversely affected by substantial amounts of nitrogen compounds in the sample. So, instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately seeks to avoid them; it warns against rather than teaches Fine's invention. See *W. L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983) (error to find obviousness where references "diverge from and teach away from the invention at hand"). In the face of this, one skilled in the art would not be expected to combine a nitrogen-related detector with the Eads system. Accordingly, there is no suggestion to combine Eads and Warnick.

Likewise, the teachings of Warnick are inconsistent with the claimed invention, to some extent. The Warnick claims are directed to a gas stream from engine exhaust "continuously flowing the gaseous mixtures into the reaction chamber" to obtain "continuous readouts" of the amount of nitric oxide in the sample. The other words, it contemplates measuring the total amount of nitric oxide in a continuously flowing gaseous mixture of unseparated nitrogen constituents. By contrast, in Fine each nitrogen compound constituent of the gaseous sample is retained in the Chromatograph for an individual time period so that each exists in discrete, time-separated pulses. * By this process, each constituent may be both identified by its position in time sequence, and measured. The claimed system, therefore, diverges from Warnick and teaches advantages not appreciated or contemplated by it.

Because neither Warnick nor Eads, alone or in combination, suggests the claimed invention, the Board erred in affirming the Examiner's conclusion that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. ACS

Hosp. Sys., 732 F.2d at 1575-77, 221 USPQ at 931-33. The Eads and Warnick references disclose, at most, that one skilled in the art might find it obvious to try the claimed invention. But whether a particular combination might be "obvious to try" is not a legitimate test of patentability. *In re Geiger*, 815 F.2d 868, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *In re Goodwin*, 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978).

[2] Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* Here, the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination.

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But this court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W. L. Gore*, 721 F.2d at 1553, 220 USPQ at 312-13. It is essential that "the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made . . . to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

C. Advantage Not Appreciated by the Prior Art .

[3] The Board erred not only in improperly combining the Eads and Warnick references but also in failing to appreciate that the appealed claims can be distinguished over that combination. A material limitation of the claimed system is that the conversion to nitric oxide occur in the range of 600°C to 1700°C. The purpose of this limitation is to prevent nitrogen from other sources, such as the air, from being converted to nitric oxide and thereby distorting the measurement of nitric oxide derived from the nitrogen compounds of the sample.

The claimed nitric oxide conversion temperature is not disclosed in Warnick. Although Eads describes a preferred temperature of 675°C to 725°C, the purpose of this range is different from that of Fine. Eads requires the 675°C to 725°C range because it affords a temperature low enough to avoid formation of unwanted sulfur trioxide, yet high enough to avoid formation of unwanted sulfides. Fine's temperature range, in contrast, does not seek to avoid the formation of sulfur compounds or even nitrogen compounds. It enables the system to break down the nitrogen compounds of the sample while avoiding the destruction of background nitrogen gas. There is a partial overlap, of course, but this is mere happenstance. Because the purposes of the two temperature ranges are entirely unrelated, Eads does not teach use of the claimed range. *See In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278. The Board erred by concluding otherwise.

D. Unexpected Results .

Because we reverse for failure to establish a *prima facie* case of obviousness, we need not reach

Fine's contention that the Board failed to accord proper weight to the objective evidence of unexpected superior results. *Id.*

E. The "Flame" Claims .

[4] Claims 62, 68, 69, 79, 85 and 86 relate to the oxygen-rich flame conversion means of the claimed invention. These "flame" claims depend from either apparatus claim 60 or method claim 77. Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); *see also In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). In view of our conclusion that claims 60 and 77 are nonobvious, the dependent "flame" claims are also patentable.

Conclusion

The Board's decision affirming the Examiner's rejection of claims 60, 62, 63, 68, 69, 77, 79, 80, 85 and 86 of Fine's application as unpatentable over the prior art under 35 U.S.C. §103 is **REVERSED**.

Footnotes

Footnote *. The Solicitor argues that the contents of Attachment C of Fine's brief were not before the Board and may not properly be considered here. However, we need not rely on Attachment C. It is merely illustrative of the qualitative separation of nitrogen compounds which occurs in Fine's system. The fact that the various constituents exit at discrete intervals is shown by the specification which was before the Board and which may appropriately be considered on appeal. *See, e.g., Astra-Sjuco, A.B. v. United States Int'l Trade Comm'n*, 629 F.2d 682, 686, 207 USPQ 1, 5 (CCPA 1980) (claims must be construed in light of specification).

Dissenting Opinion Text

Dissent By:

Smith, circuit judge, dissenting.

I respectfully dissent. I am of the firm belief that the prior art references, relied upon by the PTO to establish its prima facie case of obviousness, in combination teach and suggest Fine's invention to one skilled in the art. Also, I firmly believe that Fine failed to rebut the PTO's prima facie case. On this basis, I would affirm the board's determination sustaining the examiner's rejection, pursuant to 35 U.S.C. §103, of Fine's claims on appeal before this court.

- End of Case -

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Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., et al., 227 USPQ 657 (CA FC 1985)

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., et al.

**(CA FC)
227 USPQ 657**

**Decided October 25, 1985
No. 84-1779
U.S. Court of Appeals Federal Circuit**

Headnotes

PATENTS

1. Invention -- Specific cases -- Chemical (§ 51.5093)

Federal district court committed reversible error in combining teachings of prior art to reach conclusion of obviousness of claimed subject matter and process, in substituting claimed resin, of which one of ordinary skill in art would not have knowledge, into prior art patent and concluding obviousness therefrom, in failing to consider evidence going to secondary considerations, and in failing to determine whether there was nexus between proffered evidence of secondary considerations and merits of claimed invention.

Particular patents -- Foundry Binders

3,409,579, Robins, Foundry Binder Compositions Comprising Benzylic Ether Resin, Polysiocyanate, and Tertiary Amine, holding of invalidity of claims 14 and 19 reversed.

3,485,797, Robins, Phenolic Resins Containing Benzylic Ether Linkages and Unsubstituted Para Positions, holding of invalidity of claims 1, 2, 7, and 10, reversed.

3,676,392, Robins, Resin Compositions, holding of invalidity of claim 17, reversed.

Case History and Disposition:

Appeal from District Court for the Eastern District of Michigan, Feikens, J.; 222 USPQ 688 .

Action by Ashland Oil, Inc., against Delta Resins & Refractories, Inc., et al., for patent infringement and misappropriation of trade secrets. From judgment for defendants, plaintiff appeals. Reversed.

Attorneys:

Bruce Tittel, and Wood, Herron & Evans, both of Cincinnati, Ohio (William G. Konold, Cincinnati, Ohio, on the brief) for appellant.

Donald E. Egan, and Cook, Wetzel & Egan, Ltd., both of Chicago, Ill., for appellees.

Judge:

Before Markey, Chief Judge, and Davis and Kashiwa, Circuit Judges.

Opinion Text

Opinion By:

Kashiwa, Circuit Judge.

Ashland Oil, Inc. (Ashland) appeals from the judgment of the United States District Court for the Eastern District of Michigan, Southern Division, holding claims 1, 2, 7 and 10 of U.S. Patent No. 3,485,797 (the '797 patent), claims 14 and 19 of U.S. Patent No. 3,409,579 (the '579 patent), and claim 17 of U.S. Patent No. 3,676,392 (the '392 patent) invalid under 35 U.S.C. §103. We reverse and remand.

Background

Ashland is the assignee of the three patents involved in this case, which were issued to Dr. Janis Robins. These patents are directed to certain chemical products and processes finding ultimate use in the foundry industry. One method of forming metal castings in the foundry industry involves compacting sand around a pattern to form a sand mold, removing the pattern, and then pouring molten metal into the sand mold. This process often involves the use of internal sand cores around which the molten metal flows to produce various internal configurations.

A chemical binder, for example a phenolic urethane formed by reacting a phenol-formaldehyde resin with a hardener component, such as a polyisocyanate, and a curing agent, such as a tertiary amine, is mixed with the sand, causing the sand-binder mixture to harden at a predetermined rate. After the sand mold mixture has hardened, the mixture retains its shape during the pouring of the molten metal. After the metal solidifies the binder must break down to permit the sand to be readily dislodged from the casting.

An optimized sand-binder mixture should have a slow or negligible curing period after the initial mixing of the binder with the sand, i.e., the work time, followed by a period of rapid curing. During the work time, the sand-binder mixture remains flowable, due to negligible

curing or hardening, to allow easy forming of the mixture to conform to the pattern. Rapid curing after the mold has been formed allows the sand-binder mixture to rapidly reach its hardened state, thus permitting initiation of molten metal pouring.

Ashland sued Delta Resins & Refractories, Inc. (Delta) ¹ for infringement of claims 1, 2, 7 and 10 of the '797 patent, claims 14 and 19 of

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the '579 patent and claim 17 of the '392 patent. Claims 1, 2, and 7 of the '797 patent are directed to a process for producing a phenol-formaldehyde resin which may be used in producing a chemical binder useful in the formation sand molds. Claim 10 of the '797 patent is directed to one of the resin products derived from this process.

Claim 1 of the '797 patent is a broad process claim ² directed to reacting a phenol and aldehyde in the presence of a catalyst and reads as follows:

1. A process for the preparation of phenol aldehyde reaction products which comprises reacting a phenol having the general formula wherein X, Y, and Z are hydrogen, hydrocarbon radicals, oxyhydrocarbon radicals or halogen, with an aldehyde having the general formula R'CHO wherein

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

R' is hydrogen or a hydrocarbon radical of 1-8 carbon atoms at a mole ratio of aldehyde to phenol of greater than 1,

in the liquid phase under substantially anhydrous conditions with the removal of water above 100°C and

at temperatures below about 130° C in the presence of catalytic concentrations of a soluble divalent metal salt dissolved in the reaction medium.

Claim 10 of the '797 patent is directed to a phenol-formaldehyde resin (Pep resin) ³ and reads as follows:

10. The phenol formaldehyde resin having the general formula wherein R is hydrogen, hydrocarbon radical, oxyhydrocarbon radical or halogen, meta to the hydroxyl group of the phenol; m and n are numbers the sum of which is at least two and the ratio of m-to-n is greater than one; and A is a hydrogen or a methylol group, the molar ratio of said methylol group to hydrogen being at least one. ⁴

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Claim 14 of the '579 patent ⁵ is a dependent claim ⁶ directed to a foundry mix which contains sand as the major constituent and up to 10% by weight, based upon the weight of the sand, of a binder composition. The binder composition comprises in admixture the Pep resin as described in claim 10 of the '797 patent, a hardener component comprising a liquid polyisocyanate

containing at least two isocyanate groups and a curing agent comprising a tertiary amine.

Claim 19 of the '579 patent is a dependent claim ⁷ which reads as follows:

19. The process of preparing shaped foundry products which comprises:

(a) forming a foundry mix by uniformly distributing on a foundry aggregate containing sand as the major constituent a bind

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ing amount of up to 10% based on the weight of the aggregate of a binder composition obtained by combining [a phenolic resin having the general formula wherein R is hydrogen or a phenolic substituent meta to the hydroxyl group of the phenol, m and n are numbers the sum of which is at least 2, and the ratio of m-to-n is at least 1, and X is a hydrogen or a methylol group, the molar ratio of said methylol group-to-hydrogen being at least 1] and hardener component of claim 1, said polyisocyanate being employed in a concentration of 10 to 500% by weight of the phenolic resin;

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

(b) shaping the foundry mix in a mold; and

(c) contacting the shaped foundry mix with a tertiary amine until the binder is cured.

(bracketed material added, *see supra* note 7).

Claim 17 of the '392 patent ⁸ is a dependent claim ⁹ which reads as follows:

17. A foundry mix containing sand as the major constituent, and a binding amount of up to 10 percent based on the weight of sand of the resin composition [, said resin composition comprising in admixture,

a benzylic ether resin which has the general formula wherein R is hydrogen or a phenolic substituent meta to the hydroxyl group of the phenol, m and n are numbers the sum of which is at least 2, X is an end-group from the group consisting of hydrogen and methylol, and wherein m is at least 1 and the sum of m and the number of methylol end-groups is at least two,

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

a hardener component comprising a liquid polyisocyanate containing at least two isocyanate groups and present in an amount equal to 10 to 500 weight percent based on the weight of the resin, and

a curing catalyst having a pK_b value in the range of about 7 to 11 and present in an amount equal to 0.01 to 10.0 weight percent based on the weight of the resin].

(bracketed material added, *see supra* note 9).

District Court Proceedings

The district court noted that although the ultimate question of patent validity is a legal one, the determination of obviousness lends itself to several basic factual inquiries, to wit, the scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. The court recognized that Delta, as the party asserting patent invalidity, has the burden of proving that the claimed inventions in issue would have been obvious by clear and convincing evidence. Once Delta has established a *prima facie* case of obviousness, the burden of going forward shifts to Ashland to rebut with evidence of nonobviousness, although the burden of persuasion remains with Delta.

The court found that a person of ordinary skill in the art would have a bachelor's degree in chemistry, several years experience in phenolic and urethane chemistry, and several months exposure to the foundry art.

a. '797 Resin Claim:

The court stated that Delta relied primarily upon three prior art references to support its argument that the invention set forth in claim 10 would have been obvious: (1) U.S. Patent No. 2,079,633 (the Rothrock patent); (2) N. MEGSON, PHENOLIC RESIN CHEMISTRY (Academic Press Inc. 1958); and (3) R. MARTIN, THE CHEMISTRY OF PHENOLIC RESINS (John Wiley & Sons, Inc. 1956).

Claim 10 of the '797 patent, the court stated, requires that the sum of m and n must be at least two such that Ashland's Pep resin must have at least three rings and may have up to forty. The Pep resin contains some three ring and greater molecules, along with a substantial amount of one and two ring adducts. The court

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found ¹⁰ that the process disclosed in the Rothrock patent produces claim 10 material, although having a large portion of adducts and only a small amount of three ring or greater molecules. Ashland denied that the Rothrock process produces the Pep resin of claim 10, and averred that the Rothrock resin is inferior to the Pep resin as a foundry binder because Rothrock's hydroxyl groups are modified by butyl alcohol solvents.

As to the MEGSON reference, diagram A, see Appendix, illustrates a polybenzylic ether resin within the scope of claim 10. The drawing shows phenol-formaldehyde resin molecules having an ortho-ortho orientation, connected by either bridges, and an open para position. Claim 10 requires the sum of methylene and ether bridges to be at least two, and while the molecule of the diagram does not show methylene bridges, it is still within the scope of claim 10 because it satisfies the requirement that the sum of methylene and ether bridges with its two ether bridges. Ashland's position is that MEGSON does not disclose instructions for the preparation of this polybenzylic ether resin, and further that the molecule depicted in diagram A is only a hypothetical structure postulated to be present during curing, not what is present in a room temperature reaction product.

MARTIC discloses a linear polymeric ether resin containing up to thirty-five phenol rings linked together by ether bridges in an ortho-ortho orientation. Jordan Kopac, Delta's president,

¹¹ testified that MARTIN teaches how ether linkages are formed, and how the number of ether linkages may be increased. Further, as temperature increases, some ether linkages will break down, producing methylene linkages and formaldehyde, the formaldehyde being available to cross-link the resin. The position of Ashland was that the open para position of the Pep resin allows phenol reaction at this site, an important consideration in producing a superior binder, but MARTIN teaches a structure which is para substituted.

Based upon this prior art, the court found that while no single prior art reference rendered the Pep resin of claim 10 obvious, the references taken together would have suggested that resin. See *Leinoff v. Louis Milona & Sons, Inc.*, 726 F.2d 734, 739, 220 USPQ 845, 848-49 (Fed. Cir. 1984). Therefore, Delta had sustained its burden of proving by clear and convincing evidence that the Pep resin of claim 10 would have been obvious to one of ordinary skill in the art.

The Rothrock patent, MEGSON, and MARTIN collectively suggest the critical elements of the claimed material, i.e., a phenol-formaldehyde resin containing linear polymers which consist of phenol rings connected by ether bridges or ether and methylene bridges in an ortho-ortho orientation having an unsubstituted para position.

The court held that Ashland's evidence was insufficient to rebut Delta's clear and convincing evidence that claim 10 would have been obvious to one skilled in the art in light of the prior art, and that Ashland failed to establish that one of ordinary skill in the art would have been unable to read the prior art references and "discover" the resin claimed by Robins.

b. '797 Process Claims:

The court stated that Delta had sustained its burden of proving by clear and convincing evidence that the prior art discloses reacting phenol with formaldehyde under essentially the same conditions as the Robins patent, finding that the prior art cited by Delta would have suggested to one of ordinary skill in the mid 1960s the possibility of developing the process claimed in claims 1, 2 and 7 of the '797 patent. The Rothrock patent describes a process for manufacturing phenol-formaldehyde resins, teaching a process using: (1) a formaldehyde/phenol ratio greater than 1; (2) paraformaldehyde (the anhydrous form of formaldehyde), and removal of water in some cases; a temperature range of 100-120° C; and (4) soluble metal salt catalysts, including zinc acetate.

Japanese Patent 13696/60 describes a process for producing phenol-formaldehyde initial condensates, by reacting phenol and formaldehyde: (1) under anhydrous polymerization conditions (starting with paraformaldehyde and removing water); (2) at temperatures

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above 100° C and as high as 120° C; and (3) using soluble metal salts as catalysts. Although the examples of the Japanese Patent teach of formaldehyde/phenol ratio less than 1, the specification teaches that a formaldehyde/phenol ratio greater than 1 may be used.

The prior art reference of Fraser, Hall & Raum, *Preparation of 'High-Ortho' Novolak Resins*, J. App. Chem. (Dec. 1957), teaches the effectiveness of zinc and lead as catalysts to form ortho-ortho linked phenol-formaldehyde chains, and that benzylic ether bridges are formed at reaction temperatures below 140° C.

There are differences between this prior art and the '797 process claims. The Rothrock patent does not teach removal of water above 100° C and the Fraser reference does not teach the removal of water at all. Both Rothrock and the Japanese Patent use butyl alcohol as a solvent, whereas Robins discloses the use of toluene. The '797 claims in issue, however, do not mention the use of solvents. The butyl alcohol modified resin of Rothrock is not a phenolic resin. Ashland has also argued that neither the Japanese Patent nor Fraser produce compounds with more than two rings.

But, the court stated that Ashland had failed to establish that these differences, in light of Delta's proof, are great enough to render the inventions in issue non-obvious. The cited references collectively, if not individually, teach: (1) a formaldehyde/phenol ratio greater than 1; (2) anhydrous conditions; (3) a reaction temperature range of 100-120° C; and (4) soluble metal salt catalysts. The differences between the prior art and the claims in issue are insignificant because one of ordinary skill in the art could study the prior art references and come upon the '797 process claims.

For example, one of ordinary skill could read Rothrock and recognize that varying the solvent in Example 5 and removing water -- as Rothrock did in Examples 1 and 7 - yields a process, which could be substantially similar to the '797 process, for preparing certain phenol-formaldehyde reaction products. Similarly, although the Japanese Patent and the Fraser reference do not produce compounds with greater than two rings, one of ordinary skill reading these pieces of prior art could apply his knowledge and develop a process for preparing a phenolic resin which could be substantially similar to the process of the '797 patent.

c. The '579 and '392 Foundry Binder Claims:

The '579 and '392 foundry binder systems consist of the Pep resin, a polyisocyanate hardener, and a tertiary amine catalyst for the '579 claims or a catalyst with a pKb value of about 7 to about 11 for the '392 claim.

Delta argued that the prior art, i.e., U.S. Patents Nos. 3,409,571 ('571 patent) and 3,398,122 ('122 patent) issued to Shepart and British Patent 1,031,909, disclosed the use of phenolic urethanes as foundry binders. Dr. Frisch, an expert witness, testified that Robins' foundry binder claims would not have been obvious to one skilled in the art. One skilled in the art would not expect polyurethanes to work as foundry binders since it was known in the field that reacting phenol with isocyanates results in a blocked phenol forming an unstable urethane which disassociates or reverts to phenol and isocyanates upon heating at temperatures of 140-150° C.

The court's examination of the prior art led it to conclude otherwise. While recognizing that the British Patent ¹² was technically not prior art, it was indicative of what was known to persons of ordinary skill in the art. The patent described reacting novolac resins with highly reactive divalent materials to form a soluble product which can then be thermoset to produce a foundry binder, and such a claim is made in claim 12. The court concluded that the British Patent discloses the use of phenolic urethanes as foundry binders.

The court found the Shepard patents significant in that Shepard described a novolac phenolic resin modified with a phosphorous compound, i.e., a soluble thermoplastic. Shepard's '571 patent clearly states that thermosetting products can be produced by mixing thermoplastic products with polyisocyanates, and that such thermosetting products are useful as foundry sand

binders. Based upon the foregoing, the court concluded that the use of phenolic urethanes as foundry binders was taught by the prior art.

While Ashland argued that Shepard teaches the use of a novolac resin while the '579 and '392 claims here in issue use the Pep resin, the court found this difference insufficient to warrant a finding of nonobviousness. One skilled in the art could readily sense that the Pep resin might be substituted into the Shepard patent. It was known in the prior art how ether

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bridges and OH groups react with polyisocyanates. One skilled in the art could look at MEGSON, MARTIN and the Rothrock patent, analyze their teachings in light of Shepard and the British Patent, and conclude that a polybenzylic ether resin could be plugged into Shepard to produce a phenolic urethane foundry binder.

The court found that Delta had sustained its burden of proving that one of ordinary skill in the art of phenolic chemistry would have found it obvious to use tertiary amines to promote the reaction between the Pep resin and polyisocyanates. J. SAUNDERS & K. ERISCH, POLYURETHANES: CHEMISTRY AND TECHNOLOGY (Interscience Pub. 1962, reprint 1978), teaches that at low temperatures "one normally uses a catalyst such as a tertiary amine or aluminum chloride to promote this reaction." Further, Shepard's '571 and '122 patents, and U.S. Patent Nos. 3,242,107, 3,282,896, and 3,043,794 disclose that tertiary amines in lieu of or in addition to heat promote the reaction between phenolic resins and polyisocyanates.

The court also found that Delta had sustained its burden of proof to show that the use of a curing agent with a pKb value of about 7 to about 11 to promote the reaction between the Pep resin and polyisocyanates would have been obvious to one of ordinary skill. The SAUNDERS reference disclosed work carried out in the 1940s involving catalysts with the pKb range as claimed in claim 17 of the '392 patent which showed that base strength is a controlling factor of a catalyst's effectiveness in urethane formation. Moreover, the Shepard patents and U.S. Patent Nos. 3,156,659 3,063,964, and 2,906,717 disclosed the use of various catalysts with a pKb value in the range of claim 17 to promote the reaction between phenolic resins and polyisocyanates.

d. Secondary Considerations:

The court, citing to *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied* 105 S.Ct. 172 (1984), and *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983), stated that it had considered relevant secondary considerations before reaching the conclusion that the Robins' patents would have been obvious. The court noted that there were no independent secondary considerations relevant to the '797 patent apart from its use in Isocure, the commercial foundry mix patented under the '579 patent, and Pep Set, the commercial foundry mix patented under the '392 patent.

The court found the commercial success of Isocure and Pep Set impressive, noting that Ashland had sold millions of pounds annually of these products, and that both products enjoyed an increasing market share. While noting that Ashland had granted licenses under these patent to Combustion Engineering Company and International Minerals and Chemical Company, the court further found that after Ashland lost the Milwaukee litigation Combustion Engineering sought a declaratory judgment that the patent claims here in suit were invalid, and subsequently settled for a renegotiated royalty rate decrease from 12.5% to 5%. International Minerals was found to have

gone out of the business approximately one year after it was granted a license.

The court noted that Ashland had offered proof that Isocure and Pep Set had received recognition from the foundry industry in the form of awards and write-ups in trade publications. The court, however, found this recognition directed more towards the marketing of, rather than the invention of, these products. The court found it significant that Dr. Robins had not received any recognition from the industry and only \$200 from Ashland for his role in developing Isocure and Pep Set.

The court stated that the law is well established that commercial success alone, or combined with other secondary evidence, is insufficient to establish patentability where primary indicia of patentability is lacking. After weighing Isocure and Pep Set's secondary considerations including commercial success against the primary indicia of obviousness -- disclosures in the prior art -- the court concluded that all the patent claims in suit were invalid for obviousness.

OPINION

A determination of whether the subject matter of claims in issue would have been obvious under 35 U.S.C. §103 involves factual findings with respect to: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) where relevant, objective evidence of nonobviousness, e.g., long-felt need, commercial success, failure of others, copying, unexpected results, i.e., the secondary considerations. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 674 (Fed. Cir. 1984); *Jones v. Hardy*, 727 F.2d 1524, 1527, 220 USPQ 1021, 1023 (Fed. Cir. 1984); *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 172 (1984). These factual findings serve as the foundation upon which the court bases its ultimate conclusion regarding the obviousness of the claimed sub

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ject matter as a whole. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 890, 221 USPQ 1025, 1033 (Fed. Cir. 1984). This court reviews the ultimate conclusion of obviousness as one of law on which it must exercise independent judgment. *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 1573, 220 USPQ 584, 589 (Fed. Cir. 1984).

A patent is presumed valid, and the burden of establishing invalidity as to any claim of a patent rests upon the party asserting such invalidity. 35 U.S.C. §282 (1982). The presumption of validity is a procedural device that mandates that the party asserting invalidity bears the initial burden of establishing a *prima facie* case of obviousness under 35 U.S.C. §103. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534, 218 USPQ 871, 875 (Fed. Cir. 1983). Once a *prima facie* case has been established, the burden shifts to the patentee to go forward with rebuttal evidence showing facts supporting nonobviousness. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 227 USPQ 177, 178, No. 84-1237, slip op. at 5 (Fed. Cir. September 5, 1985); *accord, In re Piaseki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). The party asserting invalidity, however, always retains the burden of persuasion of the issue of obviousness until a final judgment is rendered. *Hughes Aircraft Co. v. Untied States*, 717 F.2d 1351, 1359, 219 USPQ 473, 478 (Fed. Cir. 1983); *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875. Each fact forming the factual foundation upon which the court bases its ultimate conclusion regarding the obviousness of the claimed subject matter as a whole must be established by clear and convincing evidence.

Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984); *SSIH Equipment Co. S.A. v. United States International Trade Commission*, 718 F.2d 365, 375, 218 USPQ 678, 687 (Fed. Cir. 1983).

On appeal, however, the party subject to the adverse judgment on the issue of validity, in this case the patentee Ashland Oil, bears the burden of showing either that the district court committed reversible legal error in its ultimate conclusion as to obviousness, or that the district court's probative factual findings underlying its ultimate conclusion on obviousness were clearly erroneous.¹³ *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, 225 USPQ 26, 30 (Fed. Cir. 1985).

A. CLAIM 10 OF THE '797 PATENT -- PEP RESIN

The district court found that the Pep resin of claim 10 contained some three ring and greater molecules, along with a substantial amount of one and two ring adducts, that the process taught by the Rothrock patent produces claim 10 material, although having a large portion of adducts and only a small amount of three ring or greater molecules, that MEGSON taught phenol-formaldehyde resins having an ortho-ortho orientation, connected by ether bridges and having an open para position, and that MARTIN taught a linear polymeric ether resin having up to thirty-five phenol rings linked by ether bridges, some of these ether linkages breaking down at higher temperatures to produce methylene linkages and formaldehyde. Based upon these findings, the court concluded that the Pep resin of claim 10 of the '797 patent would have been obvious to one of ordinary skill in the art inasmuch as the Rothrock patent, MEGSON, and Martin collectively suggested the critical elements of Pep resin here at issue.

Before reviewing the factual findings made by the district court with respect to the teachings of each of the individual references, and the propriety of combining the teachings of these references, we find it appropriate to address several statements made by the district court. *See Union Carbide Corp.*, 724 F.2d at 1574, 220 USPQ at 590 (while faulty reasoning may lead to a wrong result, appellant must show not only error in reasoning but error in result).

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A.1 Combining References

First, the court stated that Ashland had failed to establish that one of ordinary skill in the art would have been unable to read the prior art references and "discover" the Pep resin claimed by Robins. The law does not impose a burden on Ashland to establish that the *combined* teachings of the individual prior art references would not have led one skilled in the art to discover the Pep resin of claim 10. The ultimate burden of establishing invalidity rests upon the party espousing such. *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875. Where the party asserting invalidity must rely upon a combination of prior art references to establish invalidity, that party bears the burden of showing some teaching or suggestion in these references which supported their use in combination. *W.L. Gore*, 721 F.2d at 1552, 220 USPQ at 312. It is legal error to place this burden on the patentee.

A.2 35 U.S.C. §282

Further, if this statement is interpreted to place upon the patentee the burden of establishing

the validity of his patents, it is at odds with established case law. Section 282 of Title 35 places the burden for the initial production of evidence, *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875, and the ultimate burden of persuasion on the issue of validity on the party asserting patent invalidity. *Hughes Aircraft*, 717 F.2d at 1359, 219 USPQ at 478; *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875. While the burden for the production of evidence shifts to the patentee once a *prima facie* case of invalidity is established, *Ralston Purina*, 227 USPQ at 178, slip op. at 5; *Piaseki*, 745 F.2d at 1472, 223 USPQ at 788, the ultimate burden remains with the party asserting invalidity, in this instance Delta, to establish that the claims of the patents here at issue are invalid. There is no burden on Ashland to establish that the claims of these patents are valid, and it is impermissible for a trial court to shift this burden to the patentee. *Jones*, 727 F.2d at 1528-29, 220 USPQ at 1025.

A.3 Evidence vis-a-vis Obviousness

The court also held that Ashland's evidence was insufficient to rebut Delta's clear and convincing evidence on the obviousness of claim 10 of the '797 patent. While on this record we cannot say that this holding by the district court was erroneous, it is open to an interpretation¹⁴ at odds with the established case law, and for this reason we set forth a brief explication of the relevant legal principles. All facts relevant to the issue of obviousness, both the facts established by the party asserting invalidity and the facts established by the rebuttal evidence submitted by the patentee, must be fully considered by the court *prior* to reaching its conclusion on obviousness. *W.L. Gore*, 721 F.2d at 1555, 220 USPQ at 314; *Stratoflex*, 713 F.2d at 1539, 218 USPQ at 879. These facts must be established by clear and convincing evidence. *Lindemann Maschinenfabrik*, 730 F.2d at 1459, 221 USPQ at 486; *SSIH Equipment*, 718 F.2d at 375, 218 USPQ at 687.

A.4 The Pep Resin

The claims of a patent measure and define the invention. *Jones*, 727 F.2d at 1024, 220 USPQ at 1024. A §103 determination requires an evaluation of the prior art references with respect to the claimed invention. *Lear Siegler*, 733 F.2d at 890, 221 USPQ at 1033; *Union Carbide*, 724 F.2d at 1574-75, 220 USPQ at 590-91. The claims here in issue are to be read and construed¹⁵ in light of the specification and prosecution history of the patent. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 932 (Fed. Cir. 1984). The district court found that the Pep resin of claim 10 contained some three ring and greater molecules, along with a substantial amount of one and two ring adducts. This finding is clearly erroneous, being based upon a misconstruction of the governing law and an interpretation of claim 10 which is erroneous as a matter of law. *Cf. Lemelson v.*

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United States, 752 F.2d 1538, 1552, 224 USPQ 526, 534 (Fed. Cir. 1985).

The novel phenol-aldehyde resin *as claimed* in claim 10 is a linear phenolic resin wherein the sum of m and n must be at least two such that the phenolic resin as claimed comprises only molecules having three or more linked-phenol rings. Claim 10 does not claim one or two ring adducts, i.e., dimethylol phenols, benzylic ethers or methylene-bridged diphenols.¹⁶ Relevant prior art for this §103 determination requires references which disclose phenolic polymers having three or more phenol rings, phenol rings linked by benzylic ether and methylene bridges, and

phenol chains having at least one terminal methylol group.

A.5 Opinion Testimony

While objective factual evidence going towards a §103 determination is preferable to statements of opinion on the issue, the nature of the matter sought to be established, as well as the strength of the opposing evidence, must be taken into consideration in assessing the probative value of expert opinion. *In re Oelrich*, 579 F.2d 86, 91, 198 USPQ 210, 215 (CCPA 1978). Opinion testimony rendered by experts must be given consideration, and while not controlling, generally is entitled to some weight. *See* FEDR. EVID, 701-704; *Orthopedic Equipment Co. v. United States*, 702 F.2d 1005, 1012, 217 USPQ 193, 199 (Fed. Cir. 1983). Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination. *Cf. In re Altenpohl*, 500 F.2d 1151, 1158, 183 USPQ 38, 44 (CCPA 1974). While the opinion testimony of a party having a direct interest in the pending litigation is less persuasive than opinion testimony by a disinterested party, it cannot be disregarded for that reason alone and may be relied upon when sufficiently convincing. *Cf. In re McKenna*, 203 F.2d 717, 720, 97 USPQ 348, 350-51 (CCPA 1953).

The district court found that the process disclosed in the Rothrock patent produced claim 10 material having a large portion of adducts, with only a small amount of three phenol ring or greater molecules. The bases for this finding were the objective teachings disclosed in the Rothrock patent, the opinion testimony given by Jordan Kopac, Delta's CEO, who although not qualified as an expert was within the category of one skilled in the art as found by the district court, *see supra* note 11, and the opinion testimony of Dr. Robert Conley, Ashland's expert witness. The court did not make any explicit credibility determinations with respect to the opinion testimony of Mr. Kopac and Dr. Conley, nor did the court give any indication as to the weight accorded this testimony.

A.6 The Rothrock Patent

The Rothrock patent disclosed a *process* for forming a heathardening unmodified phenolformaldehyde resin.¹⁷ There was no disclosure or teaching as to the chemical structure of this phenol-formaldehyde resin, i.e., what product was formed through the use of this process. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. The district court did not point to any supporting statements or teachings in the Rothrock patent as a basis for its finding that the process of Rothrock produced a claim 10 phenolic resin.

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Each element of a claim is material. *Lemelson*, 752 F.2d at 1551, 224 USPQ at 533. The process for producing the phenolic resin as claimed in claim 10 of the '797 patent requires the removal of water above 100 °C during the process.¹⁸ This removal of water occurs during the condensation stage of the '797 process wherein the previously formed phenol-formaldehyde adduct is condensed to form the claim 10 product. The specification of the '797 patent teaches the importance of removing water during the condensation step.¹⁹ There was no teaching in the Rothrock patent that water was to be removed *during* the disclosed process.²⁰

There is no presumptive correlation that two similar processes form substantially the same

product where the processes differ by a materially limiting step. *Cf. In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968) (if the prior art of record failed to disclose a method for making a claimed compound, at the time the invention was made, it cannot be legally concluded that the compound itself was in the possession of the public).

There was no objective evidence to be gleaned from the Rothrock patent which would have supported a factual finding that the Rothrock patent produced claim 10 material. Concomitantly, there was no factual support for Mr. Kopac's opinion testimony with respect to the Rothrock patent, and consequently, Mr. Kopac's opinion testimony is of little probative value in a validity determination. *Altenpohl*, 500 F.2d at 1158, 183 USPQ at 44. Accordingly, the district court committed clear error when it found that the Rothrock process produced claim 10 material.²¹

A.7 The MARTIN Reference

MARTIN, the court found, disclosed a linear polymeric ether resin containing up to thirty-five phenol rings linked in an ortho-ortho orientation by other bridges. A reference, however, must have been considered for all it taught, disclosures that diverged and taught away from the invention at hand as well as disclosures that pointed towards and taught the invention at hand. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. While MARTIN taught a polymer having the phenol rings linked together by benzylic ether bridges, as well as at least one terminal methylol group, MARTIN also taught that this polymer had an "R" substituent at the para position. MARTIN taught that this R group was a substituent other than hydrogen. The polymeric resin of claim 10, in contrast, has an open or unsubstituted para position. Not only was the para position of the MARTIN compound blocked, there was no recognition that it would have been advantageous to replace the R substituent with a hydrogen, i.e., unsubstituted para position, to increase the polymer's reactivity.

A.8 The MEGSON Reference

The court found that the MEGSON reference illustrated a polybenzylic ether within the scope of claim 10, the drawing showing a phenol-formaldehyde resin molecule having ether bridge linkages at the ortho-ortho position and an open para position. The court found this molecule satisfied the m, n limitations of claim 10 by having at least two benzylic ether linking bridges, i.e., m equal to or greater than two while n equals zero.²² But,

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the MEGSON reference should also have been considered for disclosures that taught away from the invention here at issue. *Id.*, 220 USPQ at 311. The specific disclosure relied upon by the district court depicted two polymers cross-linked by a methylene derivative. Since this particular cross-linking mechanism was postulated to involve a reaction with nuclear hydrogen, the phenols of the polymers were shown as para unsubstituted, i.e., having hydrogen at the para position. The other cross-linking mechanisms, as well as a disclosure of a benzylic ether linked polymer product, depicted polymers having an "R" group at the para position. This R could have stood for hydrogen, or it could have stood for an organic radical.²³ There was no teaching in the explication of the cross-linking mechanism as to what the terminal end groups of these cross-linking structures were, i.e., there was no teaching that these cross-linking structures had a methylol terminal end group. Finally, there was uncontroverted testimony by Ashland's expert, *see supra* note 23, that the disclosure in the MEGSON reference relied upon by the district court

was a hypothetical structure.

The test of whether a particular compound described in the prior art may have been relied upon to show that the claimed subject matter at issue would have been obvious is whether the prior art provided an enabling disclosure with respect to the disclosed prior art compound. *Cf. In re Donohue*, 766 F.2d 531, 533, 226 USPQ 615, 621 (Fed. Cir. 1985); *Hoeksema*, 359 F.2d at 273-74, 158 USPQ at 598-99. Delta did not offer evidence that showed an enabling disclosure for the disclosed structure of MEGSON, while uncontroverted testimony showed the MEGSON structure to be a hypothetical structure.

A.9 Conclusion

The district court concluded, in light of the Rothrock patent, MEGSON, and MARTIN, that the Pep resin as claimed in claim 10 of the '797 patent would have been obvious. Obviousness, however, cannot be established by combining the teachings of the prior art to produce the claimed invention unless there was some teaching, suggestion or incentive in this prior art which would have made such a combination appropriate. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933; *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311. The district court did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination, nor in fact did the district court even point out what teachings from each of the references, when considered in combination, were relied upon in concluding that the invention of claim 10 would have been obvious. Nor apparently did the district court give any consideration to teachings in these references which would have led one skilled in the art away from the invention of claim 10. We would have to say that the district court used claim 10 of the '797 patent as a blueprint, and abstracted individual teachings from the Rothrock patent, MEGSON, and MARTIN to create the Pep resin of claim 10. *W.L. Gore*, 721 F.2d at 1552, 220 USPQ at 312. This was error as a matter of law.²⁴

We are not persuaded, based upon the foregoing, that the facts upon which the district court based its legal conclusion that the subject

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matter of claim 10 of the '797 patent would have been obvious were proven by clear and convincing evidence, *Lindemann Maschinenfabrik*, 730 F.2d at 1459, 221 USPQ at 486; *SSIH Equipment*, 718 F.2d at 375, 218 USPQ at 687, such that it cannot be said that Delta had satisfied its burden of proof. Nor was there a sufficient basis for the district court to combine the teachings of the Rothrock patent, MEGSON, and MARTIN. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933. The district court erred as a matter of law in concluding that the invention of claim 10 would have been obvious.

B. THE PROCESS CLAIMS OF THE '797 PATENT

The district court found that the Rothrock patent described a process for manufacturing phenol-formaldehyde resins wherein: (1) a formaldehyde/phenol ratio greater than 1 was taught; (2) the use of paraformaldehyde, the anhydrous form of formaldehyde, was disclosed; (3) a temperature range of 100-120°C was taught; (4) the removal of water was taught in certain examples; and (5) the use of soluble metal salt catalysts including zinc acetate was disclosed. One point of contention²⁵ as to what the Rothrock patent disclosed was whether Rothrock taught one skilled in the art the removal of water during the process which was consonant in scope to

the water-removal limitation of the '797 process claims.

B.1 Robins' '797 Process

Process claim 1 of the '797 patent, an independent claim, describes a material claim limitation which requires the phenolic-resin producing reaction to be conducted "under substantially anhydrous conditions with the removal of water above 100°C." The materiality of this limitation is disclosed in the '797 specification wherein it is stated that the "failure to *continuously* remove water not only affects the activity of the catalysts, but also the structure of the product formed, in permitting, for example, para-substitution," and that "the presence of water results in reaction products which cannot be cured to mechanically strong resins by the use of acidic agents at room temperature." (Our emphasis). The specification further discloses that the "process of the present invention is carried out in equipment which will provide for the *continuous* removal of water from the reaction mixture." (Our emphasis). The water-removal limitation of the process claims of the '797 patent, therefore, requires that water be continuously removed during the polymer formation stage of the reaction, *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 932 (the claim here in issue is read and construed in light of the specification), i.e., at temperatures above 100°C where the phenol-formaldehyde adduct--a mixture of dimethylol phenols, benzylic ethers and methylene-bridged phenols--is condensed to form the three-ring or greater phenolic resin.

B.2 The Rothrock Process

In contrast, the Rothrock patent in general did not teach or suggest the removal of water during the process described therein, nor was there any teaching or suggestion that the removal of water during the process was a critical limitation. More particularly, there was no teaching or suggestion that water was to be removed during the phenolic resin formation stage of the reaction, i.e., at temperatures above 100 °C. Only Example I of Rothrock disclosed a removal of water, teaching that a small amount of water which had formed on the sides of the reaction flask was removed from the resulting clear liquid formed by the process.²⁶ This water was removed, however, after the resin of the process had been formed,

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i.e., at temperatures well below 100 °C. The equipment for the process of Rothrock as disclosed in the examples did include an air condensor.²⁷ Mr. Kopac testified that there was no disclosure or teaching in the Rothrock patent of the function being performed by the air condensor, and that it could not be said with any certainty that the air condensor functioned to remove or retain water in the reaction zone during the Rothrock process. Examples II, III, IV and VII of the Rothrock patent disclosed that the reaction mixture was heated at reflux.²⁸

This disclosure would have suggested to one skilled in the art that water was not removed, nor was there any necessity for doing so, during the reaction process of Rothrock. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311 (a reference must have been considered in its entirety, for disclosures which taught away from an invention as well as disclosures which directed one to the invention). There was no clear teaching or suggestion in Rothrock that water was to be removed at any step during the condensation process disclosed therein, but rather only after the phenolic condensation was completed. Moreover, the Rothrock reference as a whole suggested that water

was retained during the reaction process. *See supra* note 27 and text following, and note 28.

The district court found that the Rothrock patent had not taught the removal of water above 100° C. Yet, the district court subsequently found that one of ordinary skill could have read Rothrock and recognized that varying the solvent in Example V and removing water--as Rothrock had done in Examples I and VII ²⁹--yielded a process which could have been substantially similar to the '797 process. These findings by the court are in direct conflict. Since the '797 process claims contain a material limitation directed to "the removal of water above 100° C", *Lemelson*, 752 F.2d at 1551, 224 USPQ at 533, and since the district court found that Rothrock did not teach removal of water above 100° C, there was no basis for the court's finding that the Kothrock process was substantially similar to the '797 process since the Rothrock process lacked this material limitation. *See supra* note 21. Accordingly, we hold that this finding of the district court is clearly erroneous.

B.3 The Japanese Patent

The Japanese Patent, the court found, described a process for producing phenol-formaldehyde initial condensates, by reacting phenol and formaldehyde: (1) under anhydrous polymerization conditions, i.e., starting with paraformaldehyde and removing water; (2) at temperatures above 100 °C and as high as 120 °C; and (3) using soluble metal salts as catalysts. Further, the district court found that although the examples in the Japanese Patent taught a formaldehyde/phenol ratio less than 1, the specification taught that this ratio could be greater than 1.

While the process disclosed in the Japanese Patent did teach the use of paraformaldehyde, or another substance having the same effectiveness, and the continuous removal of water, the Japanese Patent should have been considered in its entirety, with due consideration given to disclosures that diverged or taught away from the invention here at issue, as well as disclosures which directed one skilled in the art to the invention. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311.

The Japanese Patent disclosed a process for producing a phenol-formaldehyde initial condense in which phenol was added to a polar solvent such as ordinary alcohol, paraformaldehyde or a substance having similar effectiveness was dissolved into the phenol directly in a molar ratio range of 0.5 - 1.5 of formaldehyde/phenol, and this mixture was reacted in the presence of a weak alkaline catalyst ³⁰ with the continuous elimination of water to produce a liquid mixture of 2-methylolphenol or 2-methylolphenol and 2, 6-dimethylolphenol. This resulting liquid mixture was then acidified to induce a condensation reaction to form 2, 2'-dihydroxydiphenyl methane and/or other methylation products. The specification further taught that the hydroxide induced the ortho orientation of formaldehyde in a non-water system and that alkoxyphenoxymethane accelerated the ortho

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linkage during condensation. ³¹ The specification further taught that the process reaction could have been effected without dissolving the phenol in a polar solvent, i.e., a solvent need not be used.

In contrast, the '797 specification teaches that the soluble metal salt catalyst is a metalionically bonded to a salt radical, and that this salt radical should be that of a stronger acid,

one having a dissociation constant greater than 10^{-8} , to prevent cross-linking during the formation of the reaction product. Further, while the process claims of the '797 patent do not incorporate a specific limitation calling for the use of a solvent, the specification discloses that in the preferred embodiment of the process a non-polar organic solvent is utilized. While the Japanese Patent taught that the use of a solvent was optional, it also taught that when a solvent was used, it must have been a polar solvent. *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311.

To the extent that the district court concluded that the Japanese Patent by itself would have rendered the subject matter of the process claims of the '797 patent obvious, this conclusion is erroneous as a matter of law. The Japanese Patent clearly taught, at a minimum,³² that an alkaline catalyst, to induce the ortho orientation of the formaldehyde, was a material element of the process. *See supra* note 31. Moreover, the reaction of this process was a two stage reaction wherein the reactants were first exposed to an alkaline catalyst, and the resulting liquid mixture was then acidified to produce the final reaction product. The process claims of the '797 patent, in contrast, do not use an alkaline catalyst, nor is the '797 process a two stage reaction for the formation of a phenolic resin which requires initial reaction of the phenol and formaldehyde with an alkaline catalyst, and then the acidification of the resulting liquid mixture.

To the extent that the district court concluded that the teachings of the Japanese Patent could have been combined with the teachings of the Kothrock Patent to reach the conclusion that the subject matter of the '797 process claims would have been obvious, this conclusion is erroneous as a matter of law. *See supra* note 24. The district court did not point to any teachings or suggestions in either reference which would have led one skilled in the art to perceive an advantage to be derived from their combination. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933; *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311. In point of fact, the teachings of the two references would have led one skilled in the art away from their combination. Rothrock taught that his process could not be practiced using an alkali earth metallic hydroxide catalyst. In contrast, the Japanese Patent required such a catalyst. Rothrock required the use of a solvent, which could have been either polar or non-polar while the Japanese Patent taught that the use of a solvent was optional. Further, the Japanese Patent taught that when a solvent was used, it must be polar. The Japanese Patent also taught that the formaldehyde/phenol ratio could have a range of 0.5-1.5 while Rothrock required that the ratio must be greater than 1.

B.4 The Fraser Reference

The district court found that the Fraser reference taught the effectiveness of zinc and lead as catalysts to form ortho-ortho linked phenol-formaldehyde chains and that ether bridges were formed at reaction temperatures below 140° C. The court also found, however, that the Fraser reference did not teach the removal of water above 100° C and that the method of Fraser did not produce compounds having more than two phenol rings.

A reference, however, should also have been considered for its antithetical teachings. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. One of the critical teachings of Fraser was that the formaldehyde/phenol ratio must be less than 1, i.e., a molar excess of phenol was required for the method. It would be error as a matter of law if the district court concluded that the subject matter of the process claims of the '797 patent would have been obvious in view of the Fraser reference alone. Nor was there any teaching or suggestion that would have led one skilled in the art to combine the teachings of the Fraser reference with either

the teachings of the Rothrock patent or the teachings of the Japanese Patent, or both. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933.

B.5 Conclusion

We held *supra* that the district court's finding that the Rothrock process was substantially similar to the process of the '797 patent was clearly erroneous. Further, we are not persuaded that the other facts, discussed *supra*, which the district court relied upon in reaching its legal conclusion that the subject matter of claims 1, 2, and 7 of the '797 patent would have been obvious, were proven by clear and convincing evidence, *Lindemann Maschinenfabrik*, 730 F.2d at 1459, 221 USPQ at 486; *SSIH Equipment*, 718 F.2d at 375, 218 USPQ at 687, such that it cannot be said that Delta had sustained its burden of proof before the district court. It was error as a matter of law for the district court to conclude that processes of claims 1, 2 and 7 of the '797 patent would have been obvious.³³

C. THE CLAIMS OF THE '392 AND '579 PATENTS

Claim 17 of the '392 patent is directed to a foundry mix having sand as the major constituent and up to 10 percent by weight of sand of a resin composition. The resin composition comprises in admixture a benzylic ether resin substantially similar to the phenolic resin claimed in claim 10 of the '797 patent,³⁴ a hardener component defined as a liquid polyisocyanate, and a curing catalyst defined as a base having a pKb value in the range of about 7 to about 11. Claim 14 of the '579 patent is directed to a foundry mix similar to that of claim 17, except that the phenolic resin of the binder composition is the resin as claimed in claim 10 of the '797 patent, and the curing agent is defined as a tertiary amine. Claim 19 of the '579 patent is directed to a process for preparing foundry shapes using the foundry mix of claim 14.

C.1 General Level of Skill in the Art

The district court found that British Patent No. 1,031,909, although technically not prior art, was indicative of what was generally known during the relevant time frame to persons of ordinary skill in the foundry art. Finding that the British Patent described reacting novolac resins with highly reactive divalent materials³⁵ to produce soluble, fusible polymers which may be employed "as binders for sand (foundry resins)", the court concluded that the British Patent disclosed the use of phenolic urethanes as foundry binders.³⁶ The court also found that U.S. Patent Nos. 3,398,122 and 3,409,571 (the '122 and '571 patents, respectively), issued to Shepard, were significant for a teaching that phenolic urethanes were useful as constituents of foundry binders. Shepard, the court found, described a soluble thermoplastic, i.e., a novolac phenolic resin modified with a phosphorous compound, which could be mixed with polyisocyanates to form thermosetting products useful in foundry sand binders. Based upon the district court's findings with respect to the Shepard references, we cannot say that the district court erred in concluding that phenolic urethanes were taught as having utility in foundry binders.

C.2 The Shepard Patents

The district court found that one skilled in the art "could also readily sense that the 'Pep'

resin might be substituted into the Shepard patent." Since it was known in the prior art how ether bridges and hydroxyl groups reacted with polyisocyanates,³⁷ one of ordinary skill in the art could have looked at the Rothrock patent, MEGSON and MARTIN, analyzed their teachings in light of the Shepard patents and the British Patent,³⁸ and concluded that a polybenzylic ether resin could have been plugged into Shepard to produce a phenolic urethane foundry binder.

The district court's conclusion that the Pep resin might have been substituted for the phenolic condensate used in the Shepard patent is erroneous as a matter of law, for several alternative reasons.³⁹ First, the district court failed to consider the '571 patent in its entirety in particular for these teachings therein that would have led one skilled in the art away from the subject matter of the '392 and '579 patents. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. The specification of the '571 patent taught that the thermoplastic products of the invention could be used to produce thermosetting products by curing the thermoplastic products with agents such as, *inter alia*, polyisocyanates. The specification disclosed further that these thermoplastic products and/or thermosetting products were useful as foundry sand binders.

But, the district court failed to consider what these thermoplastic products were disclosed to comprise. The '571 specification disclosed that these thermoplastic products were polymeric esters characterized in that:

(1) a major portion of the moiety of the member of the phosphorus family has the formula:

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

in which the unsatisfied bonds are attached to aryl nuclei of the same phenolic condensate, and in which M is an atom of the phosphorus family, Y is oxygen or sulfur, and X is halogen, hydroxyl, mercapto, hydrocarbyl, hydrocarbyloxy, halogen-substituted hydrocarbyl, halogen-substituted hydrocarbyloxy, or an aryloxy radical of the same phenolic condensate to which M is attached;

(2) at least 60 percent of the phenol-aldehyde or phenol-ketone condensate had o,o'-alkylidene linkages, and;

(3) the phenolic condensate has an average number of aryl nuclei per molecule in the range of 2.2 to 8.

Thus, the '571 specification taught that the thermoplastic product was more than a phenolic condensate. It was a phenolic condensate wherein a phosphorus-containing moiety had its unsatisfied bonds attached to the aryl nuclei of the same phenolic condensate. Even assuming *arguendo* that one skilled in the art might readily have sensed that the Pep resin of the '797 patent might have been used as the phenolic condensate called for by the Shepard patent, Shepard taught only that it was the polymeric ester or thermoplastic product, i.e., the phenolic condensate in combination with the bonded phosphorus-containing moiety, that could be reacted with polyisocyanates or tertiary amines to produce thermosetting products having utility in foundry sand binders. But, the teachings of Shepard did not disclose to one skilled in the art whether the phenolic condensate, by itself, would have had utility as a thermosetting product.

The district court found that one of ordinary skill in the art would have looked at the

Rothrock patent, MEGSON, and MARTIN, analyzed their teachings in light of the Shepard and British patents,⁴⁰ and concluded that a polybenzylic ether resin could have been plugged into Shepard to produce a phenolic urethane binder. Based upon our holdings in Section "A. CLAIM 10 OF THE '797 PATENT -- PEP RESIN," *supra*, this conclusion is erroneous as a matter of law. In Section A we held that the Rothrock patent, MEGSON, and MARTIN, considered singly would not have led to the conclusion that the Pep resin as claimed in claim 10 of the '797 patent would have been obvious, and that there was no basis for combining the teachings of these references, such that one skilled in the art would not

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have had knowledge of the Pep resin as of the critical period. Therefore, there was no proper basis for the district court to conclude that one skilled in the art, even with knowledge of the teaching of the Shepard patent with respect to the utility of phenolic urethanes as foundry binders, would have had knowledge of a phenolic resin substantially similar to the phenolic resin as claimed in claim 10 of the '797 patent. Therefore, it was erroneous to conclude that the Pep resin of the '797 patent could have been substituted into the Shepard patent for use in producing a phenolic urethane foundry binder as taught in the Shepard patent.

C.3 Combining Prior Art with the Shepard Patents

Moreover, assuming for the sake of argument that the Rothrock patent, MEGSON, and MARTIN would have led one skilled in the art to a phenolic resin substantially similar to the phenolic resin as claimed in claim 10 of the '797 patent, the '571 patent contained relatively little in the way of positive suggestion or inference which would have led one skilled in the art to combine the teachings of these references with the Shepard patent. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933. The '571 patent taught two methods for the preparation of phenolic condensates having a high percentage of ortho-ortho alkylidene linkages.

The preferred phenolic condensate was prepared by reacting an excess of phenol with formaldehyde, i.e., a phenol/formaldehyde ratio greater than 1, in the presence of an inorganic alkali catalyst. In contrast, the Rothrock patent taught a formaldehyde/phenol ratio of 1:1, or a range of 1:63 to 1:1. Further, the Rothrock patent taught that the resins thereof could not be produced in the presence of alkali catalysts.

The alternative process for producing the phenolic condensates described in the '571 patent involved reacting an aldehyde with a phenol in the presence of an acid catalyst. The ratio of formaldehyde/phenol was described as being in the range of 0.5 to 1.0, with the preferred range being 0.7 to 0.9. Thus, while the '571 patent taught a formaldehyde/phenol ratio range wherein the upper bound minimally overlapped the lower bound of the Rothrock patent formaldehyde/phenol ratio, the preferred range taught in the '571 patent diverged away from the ratio as taught in Rothrock. The '571 patent also taught that the acid catalyst could be hydrochloric, sulfuric or oxalic acids, and was silent as to the need for a solvent to effect condensation. The Rothrock patent, in contrast, taught that condensation occurred in the presence of both a mild acid catalyst, such as zinc acetate, boric acid, or copper acetate, and a completely volatile, non-gum-forming solvent, and further that resins could not be produced in the presence of strongly acidic catalysts, such as hydrochloric acid. Since the '571 patent appeared to have suggested stronger acid catalysts than those usable in the Rothrock patent, and was silent as to the use of a solvent, an uncertainty would have arisen as to whether the teachings of the Rothrock patent could have properly been combined with the teachings of the Shepard

patent.

A further point is that the '571 patent taught that the phenolic condensate of the novel ester was one having at least 60 percent ortho-ortho alkylidene linkages. The specification disclosed that the term alkylidene expressed the structural relationship of the substituted methylene residues of the aldehyde to the phenolic nuclei of the phenolic condensates and that the term was intended to be generic to all such substituted methylene groups defined within the scope of the invention, and further taught that the phenolic condensates most useful in the invention were characterized by R₂-C-R₂ linkages, wherein R₂ could be independently selected from the group consisting of hydrogen, a hydrocarbon radical, and a halogen-substituted hydrocarbon radical. This teaching would have seemed to preclude the teachings of the Rothrock patent being combined with the teachings of the '571 patent inasmuch as the phenolic resin of the Rothrock patent which would have been substantially similar to the resin as claimed to claim 10 of the '797 patent would have had a majority of ether linkages,⁴¹ not alkylidene linkages.

D. SECONDARY CONSIDERATIONS

The district court stated that it had considered relevant⁴² secondary considerations prior

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to reaching conclusion that the subject matter of the claims in issue of the '392 and '579 patents would have been obvious. Thus, the district court seemingly recognized the holdings of this court vis-a-vis secondary considerations, to wit, that all relevant evidence going to the issue of obviousness/nonobviousness, which includes properly presented evidence on secondary considerations, must have been considered prior to reaching a conclusion on obviousness/nonobviousness. *Fromson*, 755 F.2d at 1556-57, 225 USPQ at 32; *W.L. Gore*, 721 F.2d at 1555, 220 USPQ at 314.

The district court, however, also averred that the law was well established that commercial success alone, or considered in combination with other secondary considerations, is insufficient to establish patentability where primary indicia of patentability was lacking.⁴³ Just as it is legal error for a district court to fail to consider relevant evidence going to secondary considerations, *Lindemann Maschinenfabrik*, 730 F.2d at 1461, 221 USPQ at 488, it may be legal error for a district court to presuppose that all evidence relating to secondary considerations, when considered with the other *Graham*⁴⁴ indicia relating to the obviousness/nonobviousness issue, cannot be of sufficient probative value to elevate the subject matter of the claimed invention to the level of patentable invention. *Fromson*, 755 F.2d at 1556-57, 225 USPQ at 32; *Union Carbide*, 724 F.2d at 1573, 220 USPQ at 589 (this court reviews the issue of obviousness as one of law on which it must exercise independent judgment--we must be convinced not only that the decision maker engaged in faulty analysis in applying the law to the facts, but also that a correct application of the law to those facts would bring a different result).

The objective evidence of secondary considerations may in any given case be entitled to more or less weight, depending upon its nature and its relationship to the merits of the invention. *Stratoflex*, 713 F.2d at 1539, 218 USPQ at 879. Secondary considerations may be the most pertinent, probative, and revealing evidence available to the decision maker in reaching a conclusion on the obviousness/nonobviousness issue. *W.L. Gore*, 721 F.2d at 1555, 220 USPQ at 314.

While it is incumbent upon the decision maker to recognize that evidence of secondary considerations need not be necessarily conclusive on the obviousness/nonobviousness issue, *Fromson*, 755 F.2d at 1557, 225 USPQ at 32, the decision maker must also bear in mind that, under certain circumstances, the evidence of secondary considerations may be particular

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ly strong and entitled to such weight that it may be decisive. For example, in *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575-76, 222 USPQ 744, 747 (Fed. Cir. 1984), the trial court concluded that the claimed invention would have been obvious in light of the teachings of the prior art. But, the trial court had failed to consider the evidence going to secondary considerations in arriving at this conclusion. Holding that the trial court erred as a matter of law by failing to consider the evidence of secondary considerations prior to arriving at its legal conclusion, this court, after considering the teachings of the prior art and the secondary considerations, reversed the decision of the district court.

While the district court in this case found the evidence of commercial success of the chemical sand binders claimed in the '392 and '579 patents impressive, the court found countervailing considerations in the evidence that: (1) after the Milwaukee litigation, *see supra* note 5, one Ashland licensee had effected a downward renegotiation of its royalty payment after initiating a declaratory judgment action against Ashland on the patent claims here in issue; (2) another Ashland licensee went out of the business approximately one year after the grant of the license; (3) industry recognition of the chemical sand binders as claimed in the '392 and '579 patents was directed more towards the marketing of these products rather than the invention thereof; and (4) Dr. Robins, the inventor listed in the '797, '392, and the '579 patents, had not received any recognition from the industry and only a small monetary consideration from Ashland for his role in developing these inventions. On the record before this court, we cannot say that these factual findings made by the district court were clearly erroneous. *See supra* note 13.

The record also reveals, however, that Ashland proffered other evidence of secondary considerations, to wit: (1) affidavits from its industrial customers attesting to the long-felt need satisfied by these chemical sand binders produced by Ashland; (2) the unexpected results, i.e., the "S" or "Z" cure curve, achieved by the '392 and '579 foundry mixes; and (3) the alleged copying by Delta of these chemical sand binders. The opinion rendered by the district court did not discuss these secondary considerations, *see also supra* note 42, and they apparently were not accorded any probative value or entered into the final calculus on the issue of obviousness/nonobviousness. This was error as a matter of law. *Lindemann Maschinenfabrik*, 730 F.2d at 1461, 221 USPQ at 488.

Where the evidence of record is unchallenged as to secondary considerations ignored by the decision maker, this court may, as a matter of law, consider this objective evidence in reviewing the ultimate conclusion of obviousness/nonobviousness entered by the trial court. *Id.*, 221 USPQ at 488. However, where this evidence of record is controverted, as it is in this case, this court will normally remand to the district court for its initial consideration of this evidence. Under the circumstances of this case, however, where we have held that the prior art of record is insufficient to support the legal conclusion of obviousness rendered against the '392 and '579 patents, remand for the district court's consideration of the other evidence going to secondary considerations is not necessary. Nor is it necessary for this court to determine whether a proper consideration of this evidence would have resulted in a different conclusion as to the obviousness of the '392 and '579 patents by the district court. *Union Carbide*, 724 F.2d at 1573, 220 USPQ at

589.

E. CONCLUSION

[1] We have held that the district court committed reversible error in combining the teachings of the Rothrock patent, MEGSON, and MARTIN to reach the conclusion that the subject matter of claim 10 of the '797 patent would have been obvious, and further, that these references, considered individually, would not have supported a conclusion that the subject matter of claim 10 would have been obvious.

We have further held that the district court committed reversible error in combining the teachings of the Rothrock patent, the Japanese patent, and Fraser to conclude that the invention of process claims 1, 2, and 7 of the '797 patent would have been obvious, and that these references, considered singly, would not have supported a conclusion that the invention of these process claims would have been obvious.

We have also held that, inasmuch as one of ordinary skill in the art would not have had knowledge of the Pep resin as claimed in claim 10 of the '797 patent, there was no basis to substitute this resin into the Shepard patent and conclude that the foundry binder inventions of the '392 and '579 patents would have been obvious. Further, as a matter of law there was no basis in either the Shepard patent or the other prior art relied upon by the district court which would have led one skilled in the art to combine the teachings of this prior art with the teachings of the Shepard patent.

Finally, we have held that the district court erred as a matter of law in failing to consider all evidence going to the secondary considerations. And further, that the district court erred by failing to determine if there was the

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requisite nexus between the proffered evidence of secondary considerations and the merits of the claimed inventions of the '392 and '579 patents.

Accordingly, the decision of the district court that claims 1, 2, 7 and 10 of the '797 patent, claims 14 and 19 of the '579 patent, and claim 17 of the '392 patent are invalid is reversed.

The case is remanded for consideration of the infringement issue.

REVERSED AND REMANDED.

Appendix

APPENDIX

MEGSON, PHENOLIC CHEMISTRY, 29

(Academic Press Inc. 1958)

DETAILED SURVEY

with a dimethylene ether. It is believed, however, that methylene-bridged phenols are important

constituents of resins resulting from the hardening of the alcohols, and if these are formed from the benzyl ethers, then elimination of formaldehyde should be much greater than that actually observed in the second stage of heating.

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

It appears, therefore, that much of the formaldehyde must recombine, and three methods are mentioned by which it can do this. The first involves reaction with nuclear hydrogens to give cross-linked methylene derivatives (A); the second involves reaction with phenolic hydroxyls to yield cross-linked ethers (B); the third involves reaction with methylene groups (when formed) to give cross-linked compounds of a different type (C).

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

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All these reactions would explain the low evolution of formaldehyde and the high evolution of water during the second stage of hardening.

Footnotes

Footnote 1. The voluminous record submitted by the parties did not include a complaint listing the defendants in this case. The Joint Final Pretrial Report, paragraphs 5-8, indicates that, in addition to Delta Resins & Refractories, Inc., the named defendants are the Aristo Corporation, David Horstman, Lawrence D. Kancius and Gary Lukacek.

Footnote 2. Process claim 2 further limits the reaction temperature of the process from about 110 to 120° C. Process claim 7 limits the soluble divalent metal salt to salts of lead or zinc.

Footnote 3. The district court characterized the '797 resin of claim 10 as such and we adopt this terminology. Conventional phenolic resin chemistry describes two groups of phenolic resins: resoles and novolacs. Resoles are formed by reacting a phenol with excess formaldehyde in the presence of an alkaline catalyst while novolacs are formed by reacting an excess of phenol with formaldehyde in the presence of an acidic catalyst. R. MARTIN THE CHEMISTRY OF PHENOLIC RESINS, 88 (Fig. 2) (John Wiley & Sons, Inc. 1956). The use of the process of claim 1 to form the Pep resin requires that an excess of formaldehyde be reacted with phenol in the presence of a soluble divalent metal salt catalyst. The specification of the '797 patent teaches that the salt radical of the catalyst should be that of a stronger acid. Thus, the phenolic resin formed by the process of the '797 patent, as claimed in claim 10, fails to fall squarely into either group of phenolic resins described in the prior art, resoles or novolacs.

Footnote 4. The left hand phenol depicted *supra* has been labeled so that the ortho (2, 6), meta

(3, 5) and para (4) positions are identifiable. CH₂-O-CH₂ identifies a benzylic ether bridge, CH₂ identifies a methylene bridge, OH is the chemical designation for a hydroxyl group, and CH₂OH is the chemical designation for a methylol group.

Footnote 5. In prior litigation between Ashland and Delta, claims 1, 13, 15, 16 and 18 of the '579 patent were invalidated for obviousness. *See Ashland Oil, Inc. v. Delta Oil Products*, 212 USPQ 508 (E.D. Wis. 1981), *rev'd in part*, 685 F.2d 175, 216 USPQ 857 (7th Cir. 1982), *cert. denied*, 103 S.Ct. 1769 (1983). None of these prior invalidated claims involved the Pep resin of claim 10 of the '797 patent.

Footnote 6. Claim 14 incorporates the binder composition of claim 6, claim 6 in turn being dependent upon claim 1, the broad binder composition claim of the '579 patent.

Footnote 7. Claim 19 has been redrafted in the format of claim 15, with the addition of the relevant portion of claim 6, to facilitate review. Claim 19 is dependent upon claim 15, and incorporates the phenolic resin of claim 6, i.e., the Pep resin of claim 10 of the '797 patent.

Footnote 8. In the prior action between Ashland and Delta, *see supra* note 5, the district court had held all claims of the '392 patent invalid for obviousness. The Seventh Circuit reversed in part, holding that only claims placed in issue, in that case claims 1 and 16, were subject to invalidation. The invalidated claims were not directed to the use of the Pep resin.

Footnote 9. Claim 17 incorporates the resin composition of claim 1, with the additional limitation of claim 7 wherein the phenolic resin component is a benzylic ether resin. The relevant portion of claim 7 has been incorporated into claim 17 to facilitate review.

Footnote 10. Ashland has argued that the district court made few factual findings, that the court was merely presenting the arguments of the parties. While the format of the court's opinion lends some credence to this argument, we note that the court properly recognized that it was required to make factual determinations on the scope and content of the prior art and the differences between the prior art and the Robins patents. *See Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Thus, the court's exposition appears to be the court's shorthand method of examining the prior art and the differences between the prior art and the patents in issue. Consequently, we review these statements by the court as its factual findings.

Footnote 11. During pretrial discovery Delta had identified Dr. Raymond Wentland as its only expert witness. Dr. Wentland was not called to testify during trial. Instead, Delta chose to rely primarily on the testimony of Mr. Kopac, who although possessing the qualifications of one of ordinary skill in the art, had not been qualified to testify as an expert witness.

Footnote 12. The application on the British patent was filed in London on 5 November 1963 and published on 2 June 1966. This application was based upon a prior United States application, Serial No. 241,131, filed 30 November 1962. The application on the '797 patent was filed on 14 March 1962, the application on the '392 patent had a continuation-in-part filing date of 14 March 1962 and the application on the '579 patent had a continuation-in-part filing date of 1 August 1966.

Footnote 13. A finding is clearly erroneous when the appellate court, after reviewing the entire record, is left with the definite and firm conviction that a mistake has been made, even though there is some evidence in the record to support such a finding. *United States v. U.S. Gypsum Co.*,

333 U.S. 364, 395, 76 USPQ 430, 444 (1948); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984).

Further guidance as to the role of appellate review under the clearly erroneous standard has been provided by the Supreme Court in *Anderson v. City of Bessemer City, N.C.*, 105 S.Ct. 1504, 1511, 1512 (1985), wherein the Court stated that:

This standard plainly does not entitle a reviewing court to reverse the finding of the trier of fact simply because it is convinced that it would have decided the case differently.

* * * * *

If the district court's account of the evidence is plausible in light of the record reviewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.

Footnote 14. One possible interpretation of the district court's holding is that the district court evaluated the facts established by Ashland's rebuttal evidence solely on the basis of its ability to overcome or knockdown the legal inference of obviousness, i.e., Delta's facts establishing a *prima facie* case for obviousness. This approach was rejected in *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976), wherein the court stated that facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion of obviousness, i.e., the *prima facie* case, was reached, not against the conclusion, itself. See *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 227 USPQ 177, No. 84-1237, slip op. at 5 (Fed. Cir. September 5, 1985). The ultimate conclusion on obviousness must rest upon an evaluation of *all* facts that have been established by clear and convincing evidence.

Footnote 15. Claim interpretation is a legal matter subject to review free of the clearly erroneous standard applicable to fact findings. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 127 (1984).

Footnote 16. The specification of the '797 patent teaches the formation of novel phenolic compositions characterized as a phenol-formaldehyde adduct or modified resole resin, which comprises one-ring dimethylol phenols and two-ring benzylic ethers and methylene-bridged phenols. The specification, however, also discloses that the novel phenolic resin of claim 10 is a higher molecular weight product formed by the condensation of the phenol-formaldehyde adduct. Further, the specification teaches that the "formulation of the [phenol-formaldehyde] Adduct . . . is a precursor to the novel phenolic resins [as claimed in claim 10]."

While the specification is silent as to the actual chemical composition of phenol aldehyde reaction products produced by practicing the process disclosed in the '797 patent, Dr. Robins, the inventor, testified that the phenol aldehyde reaction product resulting from this process would comprise approximately 5-10% phenol formaldehyde resin as claimed in claim 10, with the remainder being monomers such as dimethylol phenols, benzylic ethers and methylene-bridged phenols.

The actual chemical composition of the reaction products produced by the '797 process, however, is irrelevant to a §103 determination with respect to the *product* claimed in claim 10. The metes and bounds of claim 10 define the relevant product for the §103 determination. *Lear*

Siegler, 733 F.2d at 890, 221 USPQ at 1033.

Footnote 17. The Rothrock patent taught only that the phenolformaldehyde resin produced by the process disclosed therein was cured or heat-hardened by the addition of thermal energy to the resin. There was no disclosure that the resin was curable at room temperatures by the addition of an acid catalyst. The specification of the '797 patent, in contrast, teaches that the Pep resin is curable at room temperatures by the addition of an acid catalyst, or may be cured by the addition of thermal energy to the resin. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311 (a reference must have been considered in its entirety, for disclosures which taught way from the invention as well as disclosures which directed one skilled in the art towards the claimed subject matter).

Footnote 18. *See supra* note 16 and accompanying text.

Footnote 19. The presence of water results in reaction products which cannot be cured to mechanically strong resins by the use of acidic reagents at room temperature. The presence of water affects not only the activity of the catalyst, but also the structure of the product formed, for example, permitting substitution at the para position.

Footnote 20. This statement will be more fully addressed in Section "B. THE PROCESS CLAIMS OF THE '797 PATENT", *infra*.

Footnote 21. The district court's factual finding that the process of the Rothrock patent produced claim 10 material is not plausible in light of the entire record. *Anderson v. City of Bessemer City, N.C.*, 105 S.Ct. 1504, 1512 (1985). There is no objective evidence disclosed in the Rothrock patent as to the nature of the product formed by the process disclosed therein. Delta did not proffer any objective evidence as to the type of phenolic resin produced by the Rothrock process. Mr. Kopac's opinion testimony as to what the Rothrock produced is not substantiated by any objective evidence, and therefore can have probative value only as conjecture of one skilled in the art. *See* FED.R. EVID. 701. The evidence of record does not support the view of that the Rothrock process produced claim 10 material. *Id.*

Footnote 22. While we have reservations about this interpretation of claim 10, we will not, on the record before us, say it is erroneous as a matter of law. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 932. Under the court's interpretation when n is equal to zero, i.e., no methylene bridges, the ratio of m to n is undefined. But, whenever methylene bridges are present, i.e., n is a real number unequal to zero, the ratio of m to n is a finite real number. It is questionable whether the ratio of m to n would be a finite real number in all circumstances except one, where it is undefined.

The specification of the '797 patent indicates that the majority of linkages between the phenol rings will be benzylic ether such that the remainder of the linkages will be methylene. The specification also teaches that, at the temperatures at which condensation occurs to form the claim 10 material, some methylene linkages are formed.

Dr. Robins, however, gave testimony that n could equal zero, but this testimony was elicited in connection with a discussion as to whether the dimethylol phenols, benzylic ethers and methylene-bridged phenols are within the scope of claim 10. Dr. Robins also testified that the scope of claim 10 did not encompass the one or two phenol-ring adducts, but only polymers having three or more phenol rings. Dr. Conley, Ashland's expert, also testified that n could be equal to zero. *Anderson v. City of Bessemer City, N.C.*, 105 S.Ct. 1504, 1512 (1985) (where there are two permissible views of the evidence, the fact finder's choice between them cannot be

clearly erroneous). The court's interpretation of this claim appears to have been predicated on the factual testimony proffered by Ashland's witnesses.

Footnote 23. Dr. Conley testified that Megson's original work on this subject taught that the R group was an alkyl or aryl constituent. He also testified that the drawing cited by the district court, as well as the other two drawings relating to the cross-linking mechanism, were postulated or hypothetical structures to explain the cross-linking mechanism.

Footnote 24. To properly combine references A and B to reach the conclusion that the subject matter of a patent would have been obvious, case law requires that there must have been some teaching, suggestion, or inference in either reference A or B, or both, or knowledge generally available to one of ordinary skill in the relevant art, which would have led one skilled in the art to combine the relevant teachings of references A and B. *See, e.g., ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 993; *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311; *In re Sernaker*, 702 F.2d 989, 994, 217 USPQ 1, 5 (Fed. Cir. 1983). The decision maker's determination as to what objective evidence in reference A or B, or both, or generally available to one of ordinary skill in the relevant art, is of the nature of a factual finding.

The decision maker, however, after making findings as to the objective evidence, must subjectively analyze these factual findings to determine whether the teachings of references A and B could have been combined. Thus, the ultimate determination as to whether references could have been combined is a legal conclusion.

Where the district court fails to set forth the objective bases for its conclusion that references could have been combined, this court will review the determination as a matter of law.

Footnote 25. The Rothrock patent taught that formaldehyde and phenol were condensed in the presence of a mild acid catalyst *and* a completely volatile, non-gum-forming solvent selected from the class of monohydric aliphatic alcohols and mononuclear aromatic hydrocarbons. Presented testimony, and argued before the district court and this court, that the use of butyl alcohol as the Rothrock solvent produced a butyl alcohol modified resin which was not a phenolic resin. The district court made a finding of fact to this effect. Ashland, however, has ignored the teaching of Rothrock that mononuclear aromatic hydrocarbons could have been used as the solvent, and that Example V taught the use of toluene, an aromatic hydrocarbon.

Although the process claims of the '797 patent do not have a specific limitation directed to a solvent, the process claims do require that the phenol and aldehyde be "in the liquid phase." The '797 specification teaches that "[a]lthough it is not necessary to have an inert diluent present, it is generally preferred to conduct the reaction in the presence of one." The '797 specification further teaches that these solvents, when used, are non-polar organic solvents such as aliphatic, cycloaliphatic, aromatic and halogenated hydrocarbons. Toluene is set forth as a specific example of such a solvent.

Footnote 26. Contrary to the district court's statement, Example VII of the Rothrock patent did not teach the removal of water. The only statement in Example VII with respect to water was that after the completion of the process, a clear solution was obtained "with traces of water on the sides of the flask."

Footnote 27. Mr. Kopac testified that an air condensor may be used, and depending upon its length, will condense certain vapors formed during the reaction in a manner so as to reintroduce these condensed vapors back into the reaction zone while unwanted vapors are transported

outside of the reaction zone.

Footnote 28. Dr. Robins' uncontroverted testimony was that reflux meant that water was being distilled from the reaction mixture, condensed, and returned to the reaction mixture.

Footnote 29. *But see supra* note 26.

Footnote 30. At one point in the specification the Japanese Patent taught that the alkaline catalyst could be selected from a group consisting of alkaline earth metal hydroxides, magnesium hydroxide, and alkoxyphenoxymethanes -- the process disclosed therein was claimed in this manner -- while at another point in the specification it was taught that both an alkaline catalyst and the alkoxyphenoxymethanes were used to produce the initial methylolphenol products.

Footnote 31. Delta argued that the Japanese Patent emphasized the importance of removing water in the process to produce the ortho-ortho orientation of the resultant phenolic resin. The Japanese Patent, however, taught that "in order to provide the ortho orientation to the resin, it is, of course necessary to select the catalyst having the ortho orientation effect. . . ." Although it was taught that both the pH and water content of the reaction system affected the final product, the Japanese Patent clearly indicated that the alkaline catalyst was the dominant factor in producing the ortho-ortho orientation. Since the Japanese Patent disclosed that it was the anhydrous conditions and the alkaline catalyst in combination which produced the ortho-ortho orientation in the resultant product, there was no suggestion or inference therein to one skilled in the art that the removal of water in the Rothrock process, which cannot utilize an alkaline catalyst, would have been advantageous in effecting an ortho-ortho orientation in the resulting resin. *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311.

Footnote 32. *See supra* note 30.

Footnote 33. It appears that the district court used process claim 1 of the '797 patent as a blueprint, and abstracted individual teachings reference to create and process of claim 1, without due consideration for teachings in these references that would have led one skilled in the art to find it improper to combine these references. *W. L. Gore*, 721 F.2d at 1552, 220 USPQ at 312.

Footnote 34. The phenolic resin of claim 10 of the '797 patent is defined such that m and n are numbers the sum of which is at least 2 and the ratio of m to n is greater than 1. In contrast, the benzylic ether resin as claimed in the foundry mix of claim 17 of the '392 patent is defined such that m and n are numbers the sum of which is at least 2, and wherein m is at least 1.

Footnote 35. The specification described these highly reactive divalent materials as "[a]ny diisocyanate in which the isocyanate groups are the sole reactive groups. . . ."

Footnote 36. Keeping in mind the admonishment that a disclosure should have been read in its entirety for all it divulged, *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311, we have reservations about this finding of the district court. The specification of the British Patent stated that "[a]s far as [the inventors] are aware, soluble, fusible polymers which are the products of the reaction of a novolac resin and a highly reactive divalent material capable of condensing with phenolic hydroxyl groups have not heretofore been performed." The specification further stated that "the reaction of a conventional novolac polymer with such divalent reactants results in the production of the expected insoluble, infusible thermoset materials." From these disclosures in the British patent we would not say it was a foregone determination that the use of phenolic urethanes, prepared by the reaction of a resin with an isocyanate, in foundry mixes was known to those of

ordinary skill in the foundry art as of the critical date.

Footnote 37. On appeal, both Ashland and Delta have pointed out that this statement by the district court is technically incorrect in part. While polyisocyanates do react with hydroxyl groups, they do not react with benzylic ether bridges.

Footnote 38. The district court made a finding that the British Patent was not prior art. Therefore, the district court could only have utilized the British Patent in the "analysis" to the extent that the British Patent showed the general level of skill in the art as of the critical date. *Cf. In re Farrenkopf*, 713 F.2d 714, 219 USPQ 1 (Fed. Cir. 1983). *But see supra* note 36.

Footnote 39. Based upon the discussion *infra*, it is not necessary to review the factual findings made by the district court with respect to tertiary amines and curing catalysts having a pkb value in the range of about 7 to about 11.

Footnote 40. *See supra* note 38.

Footnote 41. Claim 10 of the '797 patent requires that the phenolic resin claimed therein must have a ratio of m to n of greater than 1. To satisfy this constraint, m must be greater than n such that the number of benzylic ether bridges is always greater than 50 percent. The benzylic ether bridges are defined by the chemical formula $\text{CH}_2\text{-O-CH}_2$, and as such contain oxygen. In contrast, the specification of the '571 patent teaches that the preferred phenolic condensate must have at least 60 percent ortho-ortho alkylidene bridges, and that these bridges do not contain oxygen.

Footnote 42. Case law requires that a nexus be established between the merits of the claimed invention and the evidence proffered on secondary considerations, if the evidence on secondary considerations is to be given substantial weight in the calculus of obviousness/nonobviousness. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575, 222 USPQ 744, 746 (Fed. Cir. 1984), *cert. denied*, 105 S.Ct. 2138 (1985); *Stratoflex*, 713 F.2d at 1539, 218 USPQ at 879.

Ashland argued that the merits of its phenolic urethane foundry binder mixes -- Isocure and Pep Set -- were due to the characteristics of the phenol-formaldehyde resin, i.e., the Pep resin, substantially as claimed in claim 10 of the '797 patent. *See supra* note 34 and accompanying text. The district court did not make any explicit finding as to the nexus between the merits of the claimed invention and the proffered secondary considerations.

The district court at one point in the opinion stated that the Pep resin is an ingredient in Ashland's Isocure and Pep Set foundry binder mixes. The court stated that the main advantage of these products was the speed and timing of the cure, i.e., the "S" or "Z" cure curve, which increases foundry productivity.

Delta had argued before the district court that Ashland's Isocure and Pep Set Foundry products were not covered by the '579 and '392 patents, respectively, because the Isocure and Pep Set foundry products have only an average of 2.5 phenol rings per molecule, whereas the claims of the '579 and '392 patents require an average of 3 or more phenol rings per molecule. The district court stated that since it had found the patents in suit to be invalid for obviousness under §103, there was no need to determine whether the patents in suit covered Ashland's products. This was error as a matter of law. For secondary considerations to have probative value, the decision maker must determine whether there is a nexus between the merits of the claimed

invention and the secondary considerations. *Simmons Fastener Corp.* 739 F.2d at 1575, 222 USPQ at 746; *Stratoflex*, 713 F.2d at 1539, 218 USPQ at 879. Under the circumstances of this case, Ashland's proffered evidence of secondary considerations cannot properly be considered in reaching a conclusion on obviousness/nonobviousness unless the decision maker first determines that these secondary considerations are relevant to the subject matter as claimed. For example, had the decision maker made this determination in this case, and determined that the Isocure and Pep Set produces were not covered by the '579 and '392 patents, respectively, then the secondary considerations would not have had any relevance to the obviousness/nonobviousness determination.

Footnote 43. For support for this proposition the district court cited to: *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 283, 189 USPQ 449, 453, *ren'g denied*, 426 U.S. 955 (1976) (1976) ("[P]roducing a desired result in a cheaper and faster way, and enjoying commercial success 'without invention will not make Patentability.' "); *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 153, 87 USPQ 303, 306 (1950), *reh'g denied*, 340 U.S. 918 (1951) ("But commercial success without invention will not make patentability."); and *Eltra Corp. v. Basic, Inc.*, 599 F.2d 745, 756, 202 USPQ 630, 640 (6th Cir.), *cert. denied*, 444 U.S. 942, (1979) ("Of course, commercial success and satisfaction of long-felt needs are alone not sufficient to establish that the product is the result of invention.")

Footnote 44. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

- End of Case -

Graham et al. v. John Deere Company of Kansas City et al.; Calmar, Inc. v. Cook Chemical Company; Colgate-Palmolive Company v. Same, 148 USPQ 459 (US SupCt 1966)

**Graham et al. v. John Deere Company of Kansas City et al.;
Calmar, Inc. v. Cook Chemical Company;
Colgate-Palmolive Company v. Same**

**(US SupCt)
148 USPQ 459**

**Decided Feb. 21, 1966
Nos. 11, 37, 43
U.S. Supreme Court**

Headnotes

PATENTS

1. Patentability-Invention-In general (§ 51.501)

1952 Patent Act was intended to codify judicial precedents embracing principle announced in Hotchkiss v. Greenwood, 11 How. 248; while clear language of section 103 places emphasis on inquiry into obviousness, general level of innovation necessary to sustain patentability remains the same.

2. Patent grant-In general (§ 50.01)

Federal patent power stems from Article I, Section 8 of Constitution, which is both a grant of power and a limitation; this qualified authority is limited to promotion of advances in useful arts; in exercise of patent power, Congress may not overreach restraints imposed by constitutional purpose, nor may it enlarge patent monopoly without regard to the innovation, advancement, or social benefit gained thereby; Congress may not authorize issuance of patents whose effects are to remove existent knowledge from public domain or to restrict free access to materials already available; innovation, advancement, and things which add to sum of useful knowledge are inherent requisites in patent system which must promote progress of useful arts; this is standard expressed in Constitution and it may not be ignored; within limits of constitutional grant, Congress may select policy which in its judgment best effectuates the constitutional aim; within scope established by Constitution, Congress may set out conditions and tests for patentability; it is duty of Commissioner of Patents and courts in administration of patent system to give effect to

constitutional standard by appropriate application of statutory scheme of Congress.

3. Patent grant-In general (§ 50.01)

Underlying policy of patent system is that benefit to public from the thing patented must outweigh restrictive effect of limited patent monopoly.

4. Patentability-Anticipation-In general (§ 51.201)

Patentability-Invention-In general (§ 51.501)

Patentability-Utility (§ 51.75)

Under 1952 Patent Act, patentability is dependent upon novelty, utility, and nonobviousness.

5. Patentability-Invention-In general (§ 51.501)

Patentability - Tests of - Flash of genius (§ 51.705)

Section 103 of 1952 Patent Act is a statutory expression of an additional requirement (nonobviousness) for patentability, originally expressed in *Hotchkiss v. Greenwood*, 11 How. 248; by last sentence, Congress intended to abolish test it believed Supreme Court announced in "flash of genius" phrase in *Cuno v. Automatic*, 314 U.S. 84, 51 USPQ 272; actually, "flash of genius" was mere rhetorical restatement that requirement that subject matter sought to be patented must be beyond skill of the calling; it was the device, not the invention, that had to reveal "flash of creative genius."

6. Patentability-Invention-In general (§ 51.501)

35 U.S.C. 103 was not intended by Congress to change general level of patentable invention, but was intended merely as a codification of judicial precedents embracing the *Hotchkiss* (11 How. 248) condition, with congressional directions that inquiries into obviousness of subject matter sought to be patented are a prerequisite to patentability.

7. Patentability-Invention-In general (§ 51.501)

Additional condition (nonobviousness) in 35 U.S.C. 103, when followed realistically, permits a more practical test of patentability; emphasis on nonobviousness is one of inquiry, not quality, and, as such, comports with constitutional strictures.

8. Patentability-Evidence of-Commercial success-In general (§ 51.4551)

Patentability - Evidence of - Delay and failure of others to produce invention (§ 51.459)

Patentability-Invention-In general (§ 51.501)

Patentability - Invention - Law or fact question (§ 51.507)

While ultimate question of patent validity is one of law, condition in 35 U.S.C. 103, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries; under section 103, scope and content of prior art are to be determined, differences between prior art and claims are to be ascertained, and level of ordinary skill in the pertinent art resolved; against this background, obviousness of subject matter is determined; such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to circumstances surrounding origin of subject matter sought to be patented; as indicia of obviousness, these inquiries may have relevancy.

9. Abandonment-Disclosure without claiming (§ 10.7)

Feature disclosed in patent drawings and specification, but not claimed therein, became public property.

10. Patentability-Tests of-In general (§ 51.701)

Patentability must be determined by consideration of subject matter sought to be patented taken as a whole.

11. Construction of specification and claims-By Patent Office proceedings-In general (§ 22.151)

Construction of specification and claims-By prior art (§ 22.20)

Construction of specification and claims-Claim defines invention (§ 22.30)

Invention is construed not only in light of claims, but also with reference to file wrapper or prosecution history in Patent Office; claims as allowed must be read and interpreted with reference to rejected ones and to state of prior art; claims that have been narrowed in order to obtain issuance of patent by distinguishing prior art cannot be sustained to cover that which was previously by limitation eliminated from patent.

12. Patentability - Evidence of - Commercial success-In general (§ 51.4551)

Patentability-Evidence of-Delay and failure of others to produce invention (§ 51.459)

Legal inferences or subtests (long-felt need, commercial success) focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible to judicial treatment than are technical facts often present in patent litigation; they may aid judiciary and may serve to guard against slipping into hindsight and to resist temptation to read into prior art the teachings of invention in issue; however, they do not tip scales of patentability where differences from prior art were rendered apparent by prior patent before unsuccessful attempts to solve problem; it is irrelevant that no one chose to avail himself of knowledge stored in Patent Office and make a patent search.

Particular patents-Plow Clamp

2,627,798, Graham, Clamp for Vibrating Shank Plows, claims 1 and 2 invalid.

2,870,943, Scoggin, Pump-Type Liquid Sprayer Having Hold-down Cap, claims 1 and 2 invalid.

Case History and Disposition:

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Action 1: On writ of certiorari to Court of Appeals for the Eighth Circuit; 142 USPQ 243 .
Action by William T. Graham and

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Graham Plow, Inc., against John Deere Company of Kansas City and Deere & Company for patent infringement. On writ of certiorari to review judgment for defendants. Affirmed. See also 137 USPQ 864 , 144 USPQ 780 . Action 2,3: On writs of certiorari to Court of Appeals for the Eighth Circuit; 142 USPQ 412 . Two actions against Cook Chemical Company for declaratory judgment of patent invalidity and noninfringement, one by Calmar, Inc., and one by Colgate-Palmolive Company, in which defendant counterclaims for patent infringement. On writs of certiorari to review judgments for defendant. Reversed.

See also 138 USPQ 432 , 144 USPQ 780 .

Attorneys:

Action 1: Orville O. Gold (Claude A. Fishburn on the brief) both of Kansas City, Mo., for

petitioners.

S. Thomas Morris, Amarillo, Tex. (W. W. Gibson, Amarillo, Tex., and Thomas E. Scofield, Kansas City, Mo., on the brief) for respondents.

Stanton T. Lawrence, Jr., Robert E. Isner, and Charles E. McKenney, all of New York, N.Y., filed brief for New York Patent Law Association, amicus curiae.

J. Vincent Martin, Alfred H. Evans, and Russell E. Schlorff, all of Houston, Tex., filed brief for Patent, Trademark and Copyright Section of the State Bar of Texas, amicus curiae.

Roger Robb, Washington, D.C., filed brief for American Bar Association, amicus curiae.

E. Ernest Goldstein and W. Page Keeton, both of Austin, Tex., filed brief amicus curiae.

George E. Frost and James M. Wetzel, both of Chicago, Ill., filed brief for Illinois State Bar Association, amicus curiae.

Action 2,3: Dennis G. Lyons, Washington, D.C. (Victor H. Kramer, Francis G. Cole, Watson, Cole, Grindle & Watson, and Arnold, Fortas & Porter, all of Washington, D.C., George H. Mortimer, New York, N.Y., and Howard A. Crawford, Jack W.R. Headley, and Lathrop, Righter, Gordon & Parker, all of Kansas City, Mo., on the brief) for petitioners.

Gordon D. Schmidt, Kansas City, Mo. (Hovey, Schmidt, Johnson & Hovey, Carl E. Enggas, and Watson, Ess, Marshall & Enggas, all of Kansas City, Mo., and Hugh B. Cox and Charles A. Miller, both of Washington, D.C., on the brief) for respondent.

Opinion By:

Mr. Justice Clark delivered the opinion of the Court.

Text

After a lapse of 15 years, the Court again focuses its attention on the patentability of inventions under the standard of Art. I. § 8, cl. 8. of the Constitution and under the conditions prescribed by the laws of the United States. Since our last expression on patent validity, *A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950), the Congress has for the first time expressly added a third statutory dimension to the two requirements of novelty and utility that had been the sole statutory test since the Patent Act of 1793. This is the test of obviousness, i.e., "whether the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made." Patent Act of 1952, 66 Stat. 798, 35 U.S.C. § 103 (1964 ed.).

[1] The questions, involved in each of the companion cases before us, are what effect did the

1952 Act have upon traditional statutory and judicial tests of patentability and what definitive tests are now required. We have concluded that the 1952 Act was intended to codify judicial precedents embracing the principle long ago announced by this Court in *Hotchkiss v. Greenwood*, 11 How. 248 (1850), and that, while the clear language of § 103 places emphasis on an inquiry into obviousness, the general level of innovation necessary to sustain patentability remains the same.

I.

The Cases (a). No. 11, *Graham v. John Deere Co.*, an infringement suit by petitioners, presents a conflict between two Circuits over the validity of a single patent on a "Clamp for vibrating Shank Plows." The invention, a combination of old mechanical elements, involves a device designed to absorb shock from plow shanks as they plow through rocky soil and thus to prevent damage to the plow. In 1955, the Fifth Circuit had held the patent valid under its rule that when a combination produces an "old result in a cheaper and otherwise more advantageous way," it is patentable. *Jeoffroy Mfg., Inc. v. Graham*, 219 F.2d 511, 104 USPQ 261, cert. denied, 350 U.S. 826, 107 USPQ 362. In 1964, the Eighth Circuit held, in the case at bar, that there was no new result in the patented combination and that the patent was,

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therefore, not valid. 333 F.2d 529, 142 USPQ 243, reversing 216 F.Supp. 272, 137 USPQ 864. We granted certiorari, 379 U.S. 956, 144 USPQ 780. Although we have determined that neither Circuit applied the correct test, we conclude that the patent is invalid under § 103 and, therefore, we affirm the judgment of the Eighth Circuit. (b). No. 37, *Calmar, Inc. v. Cook Chemical Co.*, and No. 43, *Colgate-Palmolive Co. v. Cook Chemical Co.*, both from the Eighth Circuit, were separate declaratory judgment actions, but were filed contemporaneously. Petitioner in *Calmar* is the manufacturer of a finger-operated sprayer with a "hold-down" cap of the type commonly seen on grocer's shelves inserted in bottles of insecticides and other liquids prior to shipment. Petitioner in *Colgate-Palmolive* is a purchaser of the sprayers and uses them in the distribution of its products. Each action sought a declaration of invalidity and noninfringement of a patent on similar sprayers issued to Cook Chemical as assignee of Baxter I. Scoggin, Jr., the inventor. By cross-action, Cook Chemical claimed infringement. The actions were consolidated for trial and the patent was sustained by the District Court. 220 F.Supp. 414, 138 USPQ 432. The Court of Appeals affirmed, 336 F.2d 110, 142 USPQ 412, and we granted certiorari, 380 U.S. 949. We reverse. Manifestly, the validity of each of these patents turns on the facts. The basic problems, however, are the same in each case and require initially a discussion of the constitutional and statutory provisions covering the patentability of the inventions.

II.

[2] At the outset it must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress "To promote the Progress of * * * useful Arts, by securing for limited Times to * * * Inventors the exclusive Right to their * * * Discoveries * * *." Art. I, § 8. ¹ The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the Sixteenth and Seventeenth Centuries by the English Crown, is limited to the promotion of advances in the "useful arts." It was written against the backdrop of the practices-eventually curtailed by the Statute of Monopolies-of the Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. See Meinhardt, *Inventions, Patents and Monopoly*, pp. 30-35

(London, 1946). The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must "promote the Progress of * * * useful Arts." This is the *standard* expressed in the Constitution and it may not be ignored. And it is in this light that patent "validity requires reference to a standard written into the Constitution." *A. & P. Tea Co. v. Supermarket Corp.*, supra, at 154, 87 USPQ at 306. Within the limits of the constitutional grant, the Congress may, of course, implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim. This is but a corollary to the grant to Congress of any Article I power. *Gibbons v. Ogden*, 9 Wheat. 1. Within the scope established by the Constitution, Congress may set out conditions and tests for patentability. *McClurg v. Kingsland*, 1 How. 202, 206. It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress. Congress quickly responded to the bidding of the Constitution by enacting the Patent Act of 1790 during the second session of the First Congress. It created an agency in the Department of State headed by the Secretary of State, the Secretary of the Department of War and the Attorney General, any two of whom could issue a patent for a period not exceeding 14 years to any petitioner that "hath invented or discovered any useful art, manufacture, or device, or any improvement therein not before known or used" if the Board found that "the invention or discovery [was] sufficiently useful and important * * *." This group, whose members administered the patent system along with their

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other public duties, was known by its own designation as "Commissioners for the Production of the Useful Arts." Thomas Jefferson, who as Secretary of State was a member of the group, was its moving spirit and might well be called the "First Administrator of our Patent System." See Federico, *Operation of the Patent Act of 1790*, 18 J. P. O. S. 237, 238 (1936). He was not only an administrator of the patent system under the 1790 Act, but was also the author of the 1793 Patent Act. In addition, Jefferson was himself an inventor of great note. His unpatented improvements on plows, to mention but one of his inventions, won acclaim and recognition on both sides of the Atlantic. Because of his active interest and influence in the early development of the patent system, Jefferson's views on the general nature of the limited patent monopoly under the Constitution, as well as his conclusions as to conditions for patentability under the statutory scheme, are worthy of note. Jefferson, like other Americans, had an instinctive aversion to monopolies. It was a monopoly on tea that sparked the Revolution and Jefferson certainly did not favor an equivalent form of monopoly under the new government. His abhorrence of monopoly extended initially to patents as well. From France, he wrote to Madison urging a bill of rights provision restricting monopoly, and as against the argument that limited monopoly might serve to incite "ingenuity," he argued forcefully that "the benefit of even limited monopolies is too doubtful to be opposed to that of their general suppression," IV Writings of Thomas Jefferson (Ford ed.), at 476 (July 1788). His views ripened, however, and in another letter to Madison after the adoption of the Bill of Rights, Jefferson stated that he would have been pleased by an express provision in this form:

"Article 9. Monopolies may be allowed to persons for their own productions in

literature, and their own inventions in the Arts, for a term not exceeding-years, but for no longer term and for no other purpose." *Id.*, at 493 (Aug. 1789).

And he later wrote:

"Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time * * *. Nobody wishes more than I do that ingenuity should receive liberal encouragement." Letter to Oliver Evans, V Writings of Thomas Jefferson, (Washington ed.), at 75 (1807). Jefferson's philosophy on the nature and purpose of the patent monopoly is expressed in a letter to Isaac McPherson, a portion of which we set out in the margin. ² He rejected a natural rights theory in intellectual property rights and clearly recognized the social and economic rationale of the patent system. The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society-at odds with the inherent free nature of disclosed ideas-and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly. Jefferson did not believe in granting patents for small details, obvious improvements, or frivolous devices. His writings evidence his insistence upon a high level of patentability. As a member of the patent board for several years, Jefferson saw clearly the

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difficulty in "drawing a line between things which are worth to the public the embarrassment of an exclusive patent and those which are not." The board on which he served sought to draw such a line and formulated several rules which are preserved in Jefferson's correspondence. ³ Despite the Board's efforts, Jefferson saw "with what slow progress a system of general rules could be matured." Because of the "abundance" of cases and the fact that the investigations occupied "more time of the members of the board than they could spare from their higher duties, the whole was turned over to the judiciary, to be matured into a system, under which everyone might know when his actions were safe and lawful." Letter to McPherson, *supra*, at 181. Apparently Congress agreed with Jefferson and the Board that the courts should develop additional, conditions for patentability. Although the Patent Act was amended, revised or codified some 50 times between 1790 and 1950, Congress steered clear of a statutory set of requirements other than the bare novelty and utility tests reformulated in Jefferson's draft of the 1793 Patent Act.

III.

[3] The difficulty of formulating conditions for patentability was heightened by the generality of the constitutional grant and the statutes implementing it, together with the underlying policy of the patent system that "the things which are worth to the public the embarrassment of an exclusive patent," as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly. The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent. This Court formulated a general condition of patentability in 1850 in *Hotchkiss v. Greenwood*, 11 How. 248. The patent involved a mere substitution of materials-porcelain or clay for wood or metal in door knobs-and the Court condemned it, holding: ⁴

"[U]nless more ingenuity and skill * * * were required than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity

which constitute essential elements of every invention. In other words, the improvement is the work of a skilled mechanic, not that of the inventor." At p. 267. Hotchkiss, by positing the condition that a patentable invention evidence more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business, merely distinguished between new and useful innovations that were capable of sustaining a patent and those that were not. The Hotchkiss test laid the cornerstone of the judicial evolution suggested by Jefferson and left to the courts by Congress. The language in the case, and in those which followed, gave birth to "invention" as a word of legal art signifying patentable inventions. Yet, as this Court has observed, "[t]he truth is the word ['invention'] cannot be defined in such a manner as to afford any substantial aid in determining whether a particular device involves an exercise of inventive faculty or not." *McClain v. Ortmayer*, 141 U.S. 419, 427 (1891), *A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. at 151, 87 USPQ at 305. Its use as a label brought about a large variety of opinions as to its meaning both in the Patent Office, in the courts, and at the bar. The Hotchkiss formulation, however, lies not in any label, but in its functional approach to questions of patentability. In practice, Hotchkiss has required a comparison between the subject matter of the patent, or patent application, and the background skill of the calling. It has been from this comparison that patentability was in each case determined.

IV.

The 1952 Act .

[4] The Act sets out the conditions of patentability in three sections. An analysis of the structure of these three sections indicates that patentability is

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dependent upon three explicit conditions: novelty and utility as articulated and defined in § 101, and § 102, and nonobviousness, the new statutory formulation, as set out in § 103. The first two sections, which trace closely the 1874 codification, express the "new and useful" tests which have always existed in the statutory scheme and, for our purposes here, need no clarification.⁵ The pivotal section around which the present controversy centers is § 103. It provides:

"§ 103. Conditions for patentability; non-obvious subject matter

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made." The section is cast in relatively unambiguous terms. Patentability is to depend, in addition to novelty and utility, upon the "non-obvious" nature of the "subject matter sought to be patented" to a person having ordinary skill in the pertinent art. The first sentence of this section is strongly reminiscent of the language in Hotchkiss. Both formulations place emphasis on the pertinent art existing at the time the invention was made and both are implicitly tied to advances in that art. The major distinction is that Congress has emphasized "non-obviousness" as the operative test of the section, rather than the less definite "invention" language of Hotchkiss that Congress thought had lead to "a large variety" of expressions in decisions and writings. In the title itself the Congress used the phrase "Conditions for patentability: *non-obvious subject matter*," thus focusing upon "non-obviousness" rather than "invention."⁶ The Senate and House

Reports, S. Rep. No. 1979, 82d Cong., 2d Sess. (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952), reflect this emphasis in these terms:

"Section 103, for the first time in our statute, provides a condition which exists in the law and has existed for more than 100 years, but only by reason of decision of the Courts. An invention which has been made, and which is new in the sense that the same thing has not been made before, may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent. That has been expressed in a large variety of ways in decisions of the courts and in writings. Section 103 states this requirement in the title. It refers to the difference between the subject matter sought to be patented and the prior art, meaning

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what was known before as described in section 102. If this difference is such that the subject matter as a whole would have been obvious at the time to a person skilled in the art, then the subject matter cannot be patented.

"That provision paraphrases language which has often been used in decisions of the courts, and the section is added to the statute for uniformity and definiteness. This section should have a stabilizing effect and minimize great departures which have appeared in some cases." H.R. Rep., at 7; S. Rep., at 6.

[5] It is undisputed that this section was, for the first time, a statutory expression of an additional requirement for patentability, originally expressed in *Hotchkiss*. It also seems apparent that Congress intended by the last sentence of § 103 to abolish the test it believed this Court announced in the controversial phrase "flash of genius," used in *Cuno Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 51 USPQ 272 (1941).⁷ It is contended, however, by some of the parties and by several of the amici that the first sentence of § 103 was intended to sweep away judicial precedents and to lower the level of patentability. Others contend that the Congress intended to codify the essential purpose reflected in existing judicial precedents—the rejection of insignificant variations and innovations of a commonplace sort—and also to focus inquiries under § 103 upon nonobviousness, rather than upon "invention," as a means of achieving more stability and predictability in determining patentability and validity. The Reviser's Note to this section,⁸ with apparent reference to *Hotchkiss*, recognizes that judicial requirements as to "lack of patentable novelty have been followed since at least as early as 1850." The note indicates that the section was inserted because it "may have some stabilizing effect and also serve as a basis for the addition at a later time of criteria which may be worked out." To this same effect are the reports of both Houses, *supra*, which state that the first sentence of the section "paraphrases the language which has often been used in decisions of the courts and the section is added to the statute for uniformity and definitiveness."

[6] We believe that this legislative history, as well as other sources,⁹ show that the revision was not intended by Congress to change the general level of patentable invention. We conclude that the section was intended merely as a codification of judicial precedents embracing the *Hotchkiss* condition, with congressional directions that inquiries into the obviousness of the subject matter sought to be patented are a prerequisite to patentability.

V.

[7] Approached in this light, the § 103 additional condition, when fol

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lowed realistically, will permit a more practical test of patentability. The emphasis on nonobviousness is one of inquiry, not quality and, as such, comports with the constitutional strictures.

[8] While the ultimate question of patent validity is one of law, *A. & P. Tea Co. v. Supermarket Corp.*, supra, at 155, 87 USPQ at 307, the § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. See Note, Subtests of "Nonobviousness," 112 U. Pa. L. Rev. 1169 (1964). This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act. While we have focused attention on the appropriate standard to be applied by the courts, it must be remembered that the primary responsibility for sifting out unpatentable material lies in the Patent Office. To await litigation is-for all practical purposes-to debilitate the patent system. We have observed a notorious difference between the standards applied by the Patent Office and by the courts. While many reasons can be adduced to explain the discrepancy, one may well be the free rein often exercised by examiners in their use of the concept of "invention." In this connection we note that the Patent Office is confronted with a most difficult task. Almost 100,000 applications for patents are filed each year. Of these, about 50,000 are granted with the result that the backlog now runs well over 200,000. United States Patent Office, Index of Patents, p. 1123 (1963). This is itself a compelling reason for the Commissioner to strictly adhere to the 1952 Act as interpreted here. This would we believe, not only expedite disposition but bring about a closer concurrence between administrative and judicial precedent.¹⁰ Although we conclude here that the inquiry which the Patent Office and the courts must make as to patentability must be beamed with greater intensity on the requirements of § 103, it bears repeating that we find no change in the general strictness with which the overall test is to be applied. We have been urged to find in § 103 a relaxed standard, supposedly a congressional reaction to the "increased standard" applied by this Court in its decisions over the last 20 or 30 years. The standard has remained invariable in this Court. Technology, however, has advanced-and with remarkable rapidity in the last 50 years. Moreover the ambit of applicable art in given fields of science has widened by disciplines unheard of a half-century ago. It is but an evenhanded application to require those persons granted the benefit of a patent monopoly be charged with an awareness of these changed conditions. The same is true of the less technical, but still useful arts. He who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office.

VI. We now turn to the application of the conditions found necessary for patentability to the

cases involved here:

A. The patent in issue in No. 11, *Graham v. John Deere Co.* This patent, No. 2,627,798 (hereinafter called the '798 patent) relates to a spring clamp which permits plow shanks to be pushed upward when they hit obstructions in the soil, and then springs the shanks back into normal position when the obstruction is passed over. The device, which we show diagrammatically in the accompanying sketches (Appendix, Fig. 1), is fixed to the plow frame as a unit. The mechanism around which the controversy centers is basically a hinge. The top

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half of it, known as the upper plate (marked 1 in the sketches), is a heavy metal piece clamped to the plow frame (2) and is stationary relative to the plow frame. The lower half of the hinge, known as the hinge plate (3), is connected to the rear of the upper plate by a hinge pin (4) and rotates downward with respect to it. The shank (5), which is bolted to the forward end of the hinge plate (at 6), runs beneath the plate and parallel to it for about nine inches, passes through a stirrup (7), and then continues backward for several feet curving down toward the ground. The chisel (8), which does the actual plowing, is attached to the rear end of the shank. As the plow frame is pulled forward, the chisel rips through the soil, thereby plowing it. In the normal position, the hinge plate and the shank are kept tight against the upper plate by a spring (9), which is atop the upper plate. A rod (10) runs through the center of the spring, extending down through holes in both plates and the shank. Its upper end is bolted to the top of the spring while its lower end is hooked against the underside of the shank. When the chisel hits a rock or other obstruction in the soil, the obstruction forces the chisel and the rear portion of the shank to move upward. The shank is pivoted (at 11) against the rear of the hinge plate and pries open the hinge against the closing tendency of the spring. (See sketch labeled "Open Position," Appendix, Fig. 1.). This closing tendency is caused by the fact that, as the hinge is opened, the connecting rod is pulled downward and the spring is compressed. When the obstruction is passed over, the upward force on the chisel disappears and the spring pulls the shank and hinge plate back into their original position. The lower, rear portion of the hinge plate is constructed in the form of a stirrup (6) which brackets the shank, passing around and beneath it. The shank fits loosely into the stirrup (permitting a slight up and down play). The stirrup is designed to prevent the shank from recoiling away from the hinge plate, and thus prevents excessive strain on the shank near its bolted connection. The stirrup also girds the shank, preventing it from fishtailing from side to side. In practical use, a number of spring-hinge-shank combinations are clamped to a plow frame, forming a set of ground-working chisels capable of withstanding the shock of rocks and other obstructions in the soil without breaking the shanks.

Background of the Patent . Chisel plows, as they are called, were developed for plowing in areas where the ground is relatively free from rocks or stones. Originally, the shanks were rigidly attached to the plow frames. When such plows were used in the rocky glacial soils of some of the Northern States, they were found to have serious defects. As the chisels hit buried rocks, a vibratory motion was set up and tremendous forces were transmitted to the shank near its connection to the frame. The shanks would break. Graham, one of the petitioners, sought to meet that problem, and in 1950 obtained a patent, U.S. No. 2,493,811, on a spring clamp which solved some of the difficulties. Graham and his companies manufactured and sold the '811 clamps. In 1950, Graham modified the '811 structure and filed for a patent. That patent, the one in issue, was granted in 1953. This suit against competing plow manufacturers resulted from charges by petitioners that several of respondents' devices infringed the '798 patent.

The Prior Art . Five prior patents indicating the state of the art were cited by the Patent Office in the prosecution of the '798 application. Four of these patents, 10 other United States patents and two prior use spring clamp arrangements not of record in the '798 file wrapper were relied upon by respondent as revealing the prior art. The District Court and the Court of Appeals found that the prior art "as a whole in one form or another contains all of the mechanical elements of the '798 Patent." One of the prior use clamp devices not before the Patent Examiner-Glencoe-was found to have "all of the elements." We confine our discussion to the prior patent of Graham, '811, and to the Glencoe clamp device, both among the references asserted by respondents. The Graham '811 and '798 patent devices are similar in all elements, save two; (1) the stirrup and the bolted connection of the shank to the hinge plate do not appear in '811; and (2) the position of the shank is reversed, being placed in patent '811 above the hinge plate, sandwiched between it and the upper plate. The shank is held in place by the spring rod which is hooked against the bottom of the hinge plate passing through a slot in the shank. Other differences are of no consequence to our examination. In practice the '811 patent arrangement permitted the shank to wobble or fishtail because it was not rigidly fixed to the hinge plate; moreover, as the hinge plate was below the

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shank, the latter caused wear on the upper plate, a member difficult to repair or replace. Graham's '798 patent application contained 12 claims. All were rejected as not distinguished from the Graham '811 patent. The inverted relationship of the shank was specifically rejected as was the bolting of the shank to the hinge plate. The Patent Office examiner found these to be "matters of design well within the expected skill of the art and devoid of invention." Graham withdrew the original claims and substituted the two new ones which are substantially those in issue here. His contention was that wear was reduced in patent '798 between the shank and the heel or rear of the upper plate. ¹¹ He also emphasized several new features, the relevant one here being that the bolt used to connect the hinge plate and shank maintained the upper face of the shank in continuing and constant contact with the underface of the hinge plate. Graham did not urge before the Patent Office the greater "flexing" qualities of the '798 patent arrangement which he so heavily relied on in the courts. The sole element in patent '798 which petitioners argue before us is the interchanging of the shank and hinge plate and the consequences flowing from this arrangement. The contention is that this arrangement - which petitioners claim is not disclosed in the prior art-permits the shank to flex under stress for its *entire* length. As we have sketched (see sketch, "Graham '798 Patent" in Appendix, Fig. 2), when the chisel hits an obstruction the resultant force (A) pushes the rear of the shank upward and the shank pivots at the underface of the upper plate at its rear (C). The natural tendency is for that portion of the shank between the pivot point and the bolted connection (i.e., between C and D) to bow downward and away from the hinge plate. The maximum distance (B) that the shank moves away from the plate is slight - for emphasis, greatly exaggerated in the sketches. This is so because of the strength of shank and the short-nine inches or so-length of that portion of the shank between (C) and (D). On the contrary, in patent '811 (see sketch, "Graham '811 Patent" in Appendix, Fig. 2), the pivot points is the upper plate at point (c); and while the tendency for the shank to bow between points (c) and (d) is the same as in '798, the shank is restricted because of the underlying hinge and cannot flex as freely. In practical effect, the shank flexes only between points (a) and (c), and not along the entire length of the shank, as in '798. Petitioners say that this difference in flex, though small, effectively absorbs the tremendous forces of the shock of obstructions whereas prior art arrangements failed.

The Obviousness of the Differences . We cannot agree with petitioners. We assume that the

prior art does not disclose such an arrangement as petitioners claim in patent '798. Still we do not believe that the argument on which petitioners' contention is bottomed supports the validity of the patent. The tendency of the shank to flex is the same in all cases. If free-flexing, as petitioners now argue, is the crucial difference above the prior art, then it appears evident that the desired result would be obtainable by not boxing the shank within the confines of the hinge.¹² The only other effective place available in the arrangement was to attach it below the hinge plate and run it through a stirrup or bracket that would not disturb its flexing qualities. Certainly a person having ordinary skill in the prior art, given the fact that the flex in the shank could be utilized more effectively if allowed to run the entire length of the shank, would immediately see that the thing to do was what Graham did, i.e., invert the shank and the hinge plate. Petitioners' argument basing validity on the free-flex theory raised for the first time on appeal is reminiscent of *Lincoln Engineering Co. v. Stewart-Warner Corp.*, 303 U.S. 545, 37 USPQ 1, 3 (1938), where the Court called such

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an effort "an afterthought. No such function * * * is hinted at in the specifications of the patent. If this were so vital an element in the functioning of the apparatus it is strange that all mention of it was omitted." At p. 550, 37 USPQ at 3. No "flexing" argument was raised in the Patent Office. Indeed, the trial judge specifically found that "flexing is not a claim of the patent in suit * * *" and would not permit interrogation as to flexing in the accused devices. Moreover, the clear testimony of petitioners' experts shows that the flexible advantages flowing from the '798 arrangement are not, in fact, a significant feature in the patent.¹³ We find no nonobvious facets in the '798 arrangement. The wear and repair claims were sufficient to overcome the patent examiner's original conclusions as to the validity of the patent. However, some of the prior art, notably *Glencoe*, was not before him. There the hinge plate is below the shank but, as the courts below found, all of the elements in the '798 patent are present in the *Glencoe* structure. Furthermore, even though the position of the shank and hinge plate appears reversed in *Glencoe*, the mechanical operation is identical. The shank there pivots about the underside of the stirrup, which in *Glencoe* is *above* the shank. In other words, the stirrup in *Glencoe* serves exactly the same function as the heel of the hinge plate in '798. The mere shifting of the wear point to the heel of the '798 hinge plate from the stirrup of *Glencoe*-itself a part of the hinge plate-presents no operative mechanical distinctions, much less nonobvious differences.

B. The Patent in issue in No. 37, *Calmar, Inc. v. Cook Chemical Co.* and in No. 43, *Colgate Palmolive Co. v. Cook Chemical Co.* The single patent¹⁴ involved in these cases relates to a plastic finger sprayer with a "hold down" lid used as a built-in dispenser for containers or bottles packaging liquid products, principally household insecticides. Only the first two of the four claims in the patent are involved here and we, therefore, limit our discussion to them. We do not set out those claims here since they are printed in 220 F.Supp., at pp. 417-418, 138 USPQ at 435. In essence the device here combines a finger-operated pump sprayer, mounted in a container or bottle by means of a container cap, with a plastic overcap which screws over the top of and depresses the sprayer (see Figure 3 in the Appendix). The pump sprayer passes through the container cap and extends down into the liquid in the container; the overcap fits over the pump sprayer and screws down on the outside of the collar mounting or retainer which is molded around the body of the sprayer. When the overcap is screwed down on this collar mounting a seal is formed by the engagement of a circular ridge or rib located above the threads on the collar mounting with a mating shoulder located inside the overcap above its threads.¹⁵ The overcap, as it is screwed down, depresses the pump plunger rendering the pump inoperable and when the seal

is effected, any liquid which might seep into the overcap through or around the pump is prevented from leaking out of the overcap. The overcap serves also to protect the sprayer head and prevent damage to it during shipment or merchandising. When the overcap is in place it does not reach the cap of the container or bottle and in no way engages it since a slight space is left between those two pieces. The device, called a shipper-sprayer in the industry, is sold as an integrated unit with the overcap in place enabling the insecticide manufacturer to install it on the container or bottle of liquid in a single operation in an automated bottling process. The ultimate consumer simply unscrews and discards the overcap, the pump plunger springs up and the sprayer is ready for use.

The Background of the Patent . For many years manufacturers engaged in the insecticide business had

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faced a serious problem in developing sprayers that could be integrated with the containers or bottles in which the insecticides were marketed. Originally, insecticides were applied through the use of tin sprayers, not supplied by the manufacturer. In 1947, Cook Chemical, an insecticide manufacturer, began to furnish its customers with plastic pump dispensers purchased from Calmar. The dispenser was an unpatented finger-operated device mounted in a perforated cardboard holder and hung over the neck of the bottle or container. It was necessary for the ultimate consumer to remove the cap of the container and insert and attach the sprayer to the latter for use. Hanging the sprayer on the side of the container or bottle was both expensive and troublesome. Packaging for shipment had to be a hand operation, and breakage and pilferage as well as the loss of the sprayer during shipment and retail display often occurred. Cook Chemical urged Calmar to develop an integrated sprayer that could be mounted directly in a container or bottle during the automated filling process and that would not leak during shipment or retail handling. Calmar did develop some such devices but for various reasons they were not completely successful. The situation was aggravated in 1954 by the entry of Colgate-Palmolive into the insecticide trade with its product marketed in aerosol spray cans. These containers, which used compressed gas as a propellant to dispense the liquid, did not require pump sprayers. During the same year Calmar was acquired by the Drackett Company. Cook Chemical became apprehensive of its source of supply for pump sprayers and decided to manufacture its own through a subsidiary, Bakan Plastics, Inc. Initially, it copied its design from the unpatented Calmar sprayer, but an officer of Cook Chemical, Scoggin, was assigned to develop a more efficient device. By 1956 Scoggin had perfected the shipper-sprayer in suit and a patent was granted in 1959 to Cook Chemical as his assignee. In the interim Cook Chemical began to use Scoggin's device and it was also marketed to the trade. The device was well received and soon became widely used. In the meanwhile, Calmar employed two engineers, Corsett and Coopridge, to perfect a shipper-sprayer and by 1958 it began to market its SS-40, a device very much similar to Scoggin's. When the Scoggin patent issued, Cook Chemical charged Calmar's SS-40 with infringement and this suit followed.

The Opinions of the District Court and the Court of Appeals. At the outset it is well to point up that the parties have always disagreed as to the scope and definition of the invention claimed in the patent in suit. Cook Chemical contends that the invention encompasses a unique combination of admittedly old elements and that patentability is found in the result produced. Its expert testified that the invention was "the first commercially successful, inexpensive, integrated shipping closure pump unit which permitted automated assembly with a container of household insecticide or similar liquids to produce a practical ready-to-use package which should be

shipped without external leakage and which was so organized that the pump unit with its hold-down cap could be itself assembled and sealed and then later assembled and sealed on the container without breaking the first seal." Cook Chemical stresses the long-felt need in the industry for such a device; the inability of others to produce it; and its commercial success-all of which, contends Cook, evidences the nonobvious nature of the device at the time it was developed. On the other hand, Calmar says that the differences between Scoggin's shipper-sprayer and the prior art relate only to the design of the overcap and that the differences are so inconsequential that the device as a whole would have been obvious at the time of its invention to a person having ordinary skill in the art. Both courts accepted Cook Chemical's contentions. While the exact basis of the District Court's holding is uncertain, it did find the subject matter of the patent new, useful and nonobvious. It concluded that Scoggin "had produced a sealed and protected sprayer unit which the manufacturer need only screw onto the top of its container much in the same fashion as a simple cap." 220 F.Supp. at 418, 138 USPQ at 436. Its decision seems to be bottomed on the finding that the Scoggin sprayer solved the long-standing problem that had confronted the industry.¹⁶ The Court of Appeals also found validity in the

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"novel 'marriage' of the sprayer with the insecticide container" which took years in discovery and in "the immediate commercial success" which it enjoyed. While finding that the individual elements of the invention were "not novel per se" the court found "nothing in the prior art suggesting Scoggin's unique combination of these old features as would solve the problem * * * which for years beset the insecticide industry." It concluded that "the * * * [device] * * * meets the exacting standard required for a combination of old elements to rise to the level of patentable invention by fulfilling the long-felt need with an economical, efficient, utilitarian apparatus which achieved novel results and immediate commercial success." 336 F.2d at 114, 142 USPQ at 415.

The Prior Art . Only two of the five prior art patents cited by the Patent Office Examiner in the prosecution of Scoggin's application are necessary to our discussion, i.e., Lohse U.S. Patent No. 2,119,884 (1938) and Mellon U.S. Patent No. 2,586,687 (1952). Others are cited by Calmar that were not before the examiner, but of these our purposes require discussion only of the Livingstone U.S. Patent No. 2,751,480 (1953). Simplified drawings of each of these patents are reproduced in the Appendix, Figs. 4-6 for comparison and description. The Lohse patent (Fig. 4) is a shipper-sprayer designed to perform the same function as Scoggin's device. The differences, recognized by the District Court, are found in the overcap seal which in Lohse is formed by the skirt of the overcap engaging a washer or gasket which rests upon the upper surface of the container cap. The court emphasized that in Lohse "there are no seals above the threads and below the sprayer head." 220 F.Supp. at 419-420. 138 USPQ at 437. The Mellon patent (Fig. 5), however, discloses the idea of effecting a seal above the threads of the overcap. Mellon's device, likewise a shipper-sprayer, differs from Scoggin's in that its overcap screws directly on the container, and a gasket, rather than a rib, is used to effect the seal. Finally, Livingstone (Fig. 6) shows a seal above the threads accomplished without the use of a gasket or washer.¹⁷ Although Livingstone's arrangement was designed to cover and protect pouring spouts, his sealing feature is strikingly similar to Scoggin's. Livingstone uses a tongue and groove technique in which the tongue, located on the upper surface of the collar, fits into a groove on the inside of the overcap. Scoggin employed the rib and shoulder seal in the identical position and with less efficiency because the Livingstone technique is inherently a more stable

structure, forming an interlock that withstands distortion of the overcap when subjected to rough handling. Indeed, Cook Chemical has now incorporated the Livingstone closure into its own shipper-sprayers as had Calmar in its SS-40.

The Invalidity of the Patent .

[10] Let us first return to the fundamental disagreement between the parties. Cook Chemical, as we noted at the outset, urges that the invention must be viewed as the overall combination, or-putting it in the language of the statute-that we must consider the subject matter sought to be patented taken as a whole. With this position, taken in the abstract there is of course no quibble. But the history of the prosecution of the Scoggin application in the Patent Office reveals a substantial divergence in respondent's present position. As originally submitted, the Scoggin application contained 15 claims which in very broad terms claimed the entire combination of spray pump and overcap. No mention of, or claim for, the sealing features were made. All 15 claims were rejected by the examiner because (1) the applicant was vague and indefinite as to what the invention was, and (2) the claims were met by Lohse. Scoggin canceled these claims and submitted new ones. Upon a further series of rejections and new submissions, the Patent Office Examiner, after an office interview, at last relented. It is crystal-clear that after the first rejection, Scoggin relied entirely upon the sealing arrangement as the exclusive patentable difference in his combination. It is likewise clear that it was on that feature that the examiner allowed the claims. In fact, in a letter accompanying the final submission of claims, Scoggin, through his attorney, stated that "agreement was reached between the Honorable Examiner and applicant's attorney relative to *limitations* which must be in the claims in order to define novelty over the previously applied disclosure of

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Lohse when considered in view of the newly cited patents of Mellon and Darley, Jr." (Italics added.) Moreover, those limitations were specifically spelled out as (1) the use of a rib seal and (2) an overcap whose lower edge did not contact the container cap. Mellon was distinguished, as was the Darley patent, *infra*, n. 18, on the basis that although it disclosed a hold-down cap with a seal located above the threads, it did not disclose a rib seal disposed in such position as to cause the lower peripheral edge of the overcap "to be maintained out of contacting relationship with [the container] cap * * * when * * * [the overcap] was screwed [on] tightly * * *." Scoggin maintained that the "obvious modification" of Lohse in view of Mellon would be merely to place the Lohse gasket above the threads with the lower edge of the overcap remaining in tight contact with the container cap or neck of the container itself. In other words, the Scoggin invention was limited to the use of a rib-rather than a washer or gasket-and the existence of a slight space between the overcap and the container cap.

[11] It is, of course, well-settled that an invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office. *Hogg v. Emerson*, 11 How. 587 (1850); *Crawford v. Heysinger*, 123 U.S. 589 (1887). Claims as allowed must be read and interpreted with reference to rejected ones and to the state of the prior art; and claims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be sustained to cover that which was previously by limitation eliminated from the patent. *Powers-Kennedy Co. v. Concrete Co.*, 282 U.S. 175, 185-186, 7 USPQ 122, 126 (1930); *Schriber Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-221, 47 USPQ 345, 348-349 (1940). Here, the patentee obtained his patent only by accepting the limitations imposed by the examiner. The claims were carefully drafted to reflect these limitations and

Cook Chemical is not now free to assert a broader view of Scoggin's invention. The subject matter as a whole reduces, then, to the distinguishing features clearly incorporated into the claims. We now turn to those features. As to the space between the skirt of the overcap and the container cap, the District Court found:

"Certainly without a space so described there could be no inner seal with the cap, but such a space is not new or novel, it is necessary to the formation of the seal within the hold-down cap.

" *To me this language is descriptive of an element of the patent, but not a part of the invention* . It is too simple, really, to require much discussion. In this device the hold-down cap was intended to perform two functions-to hold down the sprayer head and to form a solid tight seal between the shoulder and the collar below. In assembling the element it is necessary to provide this space in order to form the seal." 220 F.Supp. at 420, 138 USPQ at 437. (Italics added.) The court correctly viewed the significance of the feature. We are at a loss to explain the examiner's allowance on the basis of such a distinction. Scoggin was able to convince the examiner that Mellon's cap contacted the bottle neck while his did not. Although the drawings included in the Mellon application show that the cap might touch the neck of the bottle when fully screwed down, there is nothing-absolutely nothing-which indicates that the cap was designed at any time to *engage* the bottle neck. It is palpably evident that Mellon embodies a seal formed by a gasket compressed between the cap and the bottle neck. It follows that the cap in Mellon will not seal if it does not bear down on the gasket and this would be impractical, if not impossible, under the construction urged by Scoggin before the examiner. Moreover, the space so strongly asserted by Cook Chemical appears quite plainly on the Livingstone device, a reference not cited by the examiner. The substitution of a rib built into a collar likewise presents no patentable difference above the prior art. It was fully disclosed and dedicated to the public in the Livingstone patent. Cook Chemical argues, however, that Livingstone is not in the *pertinent* prior art because it relates to liquid containers having pouring spouts rather than pump sprayers. Apart from the fact that respondent made no such objection to similar references cited by the examiner, ¹⁸ so restricted a view of the applicable prior art is not justified. The problems confronting Scoggin and the insecticide

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industry were not insecticide problems; they were mechanical closure problems. Closure devices in such a closely related art as pouring spouts for liquid containers are at the very least pertinent references. See, II Walker, Patents § 260 (Deller ed. 1937).

[12] Cook Chemical insists, however, that the development of a workable shipper-sprayer eluded Calmar, who had long and unsuccessfully sought to solve the problem. And, further, that the long-felt need in the industry for a device such as Scoggin's together with its wide commercial success supports its patentability. These legal inferences or subtests do focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible to judicial treatment than are the highly technical facts often present in patent litigation. See Learned Hand in *Reiner v. I. Leon Co.*, 285 F.2d 501, 504, 128 USPQ 25, 27-28, cert. den. 366 U.S. 929, 129 USPQ 502 (1960). See also Comment, Subtests of "Nonobviousness," 112 Pa. L.Rev. 1169 (June 1964). Such inquiries may lend a helping hand to the judiciary which, as Mr. Justice Frankfurter observed, is most ill-fitted to discharge the technological duties cast upon it by patent legislation. *Marconi Wireless Co. v. United States*, 320 U.S. 1, 60, 57 USPQ 471, 496 (1943). They may also serve to "guard against slipping into

hindsight," *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412, 141 USPQ 549, 555 (1964), cert. denied 379 U.S. 888, 143 USPQ 465, and to resist the temptation to read into the prior art the teachings of the invention in issue. However, these factors do not, in the circumstances of this case, tip the scales of patentability: The Scoggin invention, as limited by the Patent Office and accepted by Scoggin, rests upon exceedingly small and quite nontechnical mechanical differences in a device which was old in the art. At the latest, those differences were rendered apparent in 1953 by the appearance of the Livingstone patent, and unsuccessful attempts to reach a solution to the problems confronting Scoggin made before that time because wholly irrelevant. It is also irrelevant that no one apparently chose to avail themselves of knowledge stored in the Patent Office and readily available by the simple expedient of conducting a patent search—a prudent and nowadays common preliminary to well organized research. *Mast, Foos & Co. v. Stover Mfg. Co.*, 177 U.S. 485 (1900). To us, the limited claims of the Scoggin patent are clearly evident from the prior art as it stood at the time of the invention. We conclude that the claims in issue in the Scoggin patent must fall as not meeting the test of § 103, since the differences between them and the pertinent prior art would have been obvious to a person reasonably skilled in that art. The judgment of the Court of Appeals in No. 11 is affirmed. The judgment of the Court of Appeals in Nos. 37 and 43 is reversed and the cases remanded to the District Court for disposition not inconsistent with this opinion. *It is so ordered* Mr. Justice Stewart took no part in the consideration or decision of Nos. 37 and 43. Mr. Justice Fortas took no part in the consideration or decision of these cases.

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Footnotes

Footnote 1. The provision appears in the Constitution spliced together with the copyright provision, which we omit as not relevant here. See H.R. Rep. No. 1923, 82d Cong., 2d Sess., at 4 (1952); DeWolf, *An Outline of Copyright Law*, p. 15 (Boston 1925).

Footnote 2. "Stable ownership is the gift of social law, and is given late in the progress of society. It would be curious, then, if an idea, the fugitive fermentation of an individual brain, could, of natural right, be claimed in exclusive and stable property. If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening mine. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature. When she made them like fire, expansible over all space, without lessening their density in any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation. Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done according to the will and convenience of the society, without claim or complaint from anybody." VI Writings of Thomas Jefferson (Washington ed.), at 180 (1814).

Footnote 3. "A machine of which we are possessed might be applied by every man to any use of which it is susceptible." Letter to Isaac McPherson, *supra*, at 181.

"A change of material should not give title to a patent. As the making a plowshare of cast rather than of wrought iron; a comb of iron instead of horn or ivory * * *." *Ibid*.

"A mere change of form should give no right to a patent, as a high quartered shoe instead of a low one; a round hat instead of a three square, or a square bucket instead of a round one." *Id.*, at 182.

"[A combined use of old implements] A man has the right to use a saw, an axe, a plane separately; may he not combine their uses on the same piece of wood?" Letter to Oliver Evans, *supra*, at 298.

Footnote 4. In historical retrospect, the specific result in Hotchkiss flows directly from an application of one of the rules of the original board of "Commissioners," n. 3, second rule, *supra*.

Footnote 5. "§ 101. Inventions patentable

"Whoever invents or discovers any new and useful process, machine, manufacture, or

composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

"§ 102. Conditions for patentability; novelty and loss of right to patent

"A person shall be entitled to a patent unless-

"(a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

"(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

"(c) he has abandoned the invention, or

"(d) the invention was first patented or caused to be patented by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application filed more than twelve months before the filing of the application in the United States, or

"(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or

"(f) he did not himself invent the subject matter sought to be patented, or

"(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

The precursors of these sections are to be found in Act of February 21, 1793, c. 11, 1 Stat. 318; Act of July 4, 1836, c. 357, 5 Stat. 117; Act of July 8, 1870, c. 230, 16 Stat. 198; Rev. Stat. (1874) § 4886.

Footnote 6. The corresponding provision in the preliminary draft was titled "Conditions for Patentability; *lack of invention*," Proposed Revision and Amendment of the Patent Laws, Preliminary Draft with Notes of House Committee on the Judiciary (Committee Print, 1950).

Footnote 7. The sentence in which the phrase occurs reads: "The new device, however useful it may be, must reveal the flash of creative genius, not merely the skill of the calling." At p. 91, 51 USPQ at 275. Although some writers and lower courts found in the language connotations as to the frame of mind of the inventors, none were so intended. The opinion approved Hotchkiss specifically, and the reference to "flash of creative genius" was but a rhetorical embellishment of language going back to 1833. Cf. "exercise of genius," Shaw v. Cooper, 7 Pet. 292; "inventive genius," Rickendorfer v. Farber, 92 U.S. 347 (1875); Concrete Appliance Products Co.; "flash or thought," Densmore v. Scofield, 102 U.S. 375 (1880); "intuitive genius," C. A. Potts Co. v. Creager, 155 U.S. 597 (1895). Rather than a more exacting standard, Cuno merely rhetorically restated the requirement that the subject matter sought to be patented must be beyond the skill of the calling. It was the device, not the invention, that had to reveal the "flash of creative genius."

See Boyajian, *The Flash of Creative Genius*, 25 J.P.O.S. 776, 780, 781 (1943); *Pacific Contact Laboratories, Inc. v. Solex Laboratories, Inc.*, 209 F.2d 529, 533, 100 USPQ 12, 12; *Brown & Sharpe Mfg. Co., v. Kar Engineering Co.*, 154 F.2d 48, 51-52, 68 USPQ 427, 427; *In re Shortell*, 142 F.2d 292, 295-296, 61 USPQ 362, 366-367.

Footnote 8. "There is no provision corresponding to the first sentence explicitly stated in the present statutes, but the refusal of patents by the Patent Office, and the holding of patents invalid by the courts, on the ground of lack of invention or lack of patentable novelty has been followed since at least as early as 1850. This paragraph is added with the view that an explicit statement in the statute may have some stabilizing effect, and also to serve as a basis for the addition at a later time of some criteria which may be worked out.

"The second sentence states that patentability as to this requirement is not to be negated by the manner in which the invention was made, that is, it is immaterial whether it resulted from long toil and experimentation or from a flash of genius."

Footnote 9. See *Efforts to Establish a Statutory Standard of Invention*, Study No. 7, Senate Subcommittee on Patents, Trademarks and Copyrights, 85th Cong., 2d Sess. (Committee Print, 1961); *Hearings, Subcommittee No. 3, House Committee on the Judiciary, on H.R. 3760*, 82d Cong., 1st Sess. (1951).

Footnote 10. The President has appointed a Commission on the Patent System. Executive Order No. 11215, 30 Fed. Reg. 4661 (April 10, 1965). It is hoped that its studies may develop more efficient administrative procedures and techniques that will further expedite dispositions and at the same time insure the strict application of appropriate tests of patentability.

Footnote 11. In '811, where the shank was above the hinge plate, an upward movement of the chisel forced the shank up against the underside of the rear of the upper plate. The upper plate thus acted as the fulcrum about which the hinge was pried open. Because of this, as well as the location of the hinge pin, the shank rubbed against the heel of the upper plate causing wear both to the plate and to the shank. By relocating the hinge pin and by placing the hinge plate between the shank and the upper plate, as in 798, the rubbing was eliminated and the wear point was changed to the hinge plate, a member more easily removed or replaced for repair.

Footnote 12. Even petitioners' expert testified to that effect:

"Q. Given the same length of the forward portion of the clamp * * * you would anticipate that the magnitude of flex [in 798] would be precisely the same or substantially the same as in 811, wouldn't you?

"A. I would think so."

Footnote 13. "Q. * * * Do you regard the small degree of flex in the forward end of the shank that lies between the pivot point and the point of spring attachment to be of any significance or any importance to the functioning of a device such as 798? A. Unless you are approaching the elastic limit, I think this flexing will reduce the maximum stress at the point of pivot there, where the maximum stress does occur. I think it will reduce that. I don't know how much.

"Q. Do you think it is a substantial factor, a factor of importance in the functioning of the structure? A. Not a great factor, no."

The same expert previously testified similarly in *Jeoffroy*, *supra*.

Footnote 14. The patent is U.S. No. 2,870,943 issued in 1959 to Cook Chemical Co. as assignee of Burton I. Scoggin, Jr., the inventor. In No. 37 Calmar is the manufacturer of an alleged infringing device, and, in No. 43, Colgate is a purchaser of Calmar and user of its device.

Footnote 15. Our discussion here relates to the overcap seal. The container itself is sealed in the customary way through the use of a container gasket located between the container and the container cap.

Footnote 16. "By the same reasoning, may it not also be said that if [the device] solved a long-sought need, it was likewise novel? If it meets the requirements of being new, novel, and useful, it was the subject of invention, although it may have been a short step, nevertheless it was the last step that ended the journey. The last step is the one that wins and he who takes it when others could not, is entitled to patent protection." 220 F.Supp. at 421, 138 USPQ at 438.

Footnote 17. [9] While the sealing feature was not specifically claimed in the Livingstone patent, it was disclosed in the drawings and specifications. Under long-settled law the feature became public property. *Miller v. Brass Company*, 104 U.S. 350, 352 (1881).

Footnote 18. In addition to Livingstone and Mellon, the examiner cited Slade, U.S. Patent No. 2,844,290 (hold-down cap for detergent cans having a pouring spout); Nilson, U.S. Patent No. 2,118,222 (combined cap and spout for liquid dispensing containers); Darley, Jr., U.S. Patent No. 1,447,712 (containers for toothpaste, cold creams and other semi-liquid substances).

- End of Case -

Interconnect Planning Corporation v. Feil, et al.□

(CA FC)
227 USPQ 543

Decided October 9, 1985
Nos. 84-1467 and 85-565
U.S. Court of Appeals Federal Circuit

Headnotes

PATENTS

1. Estoppel -- As to validity -- In general (§ 35.151)

Federal district court decision on patent validity, which was not final, not certified, not appealed, and mooted by subsequent events, does not collaterally estop appeal of those aspects of subsequent decision on reissue of patent which are "common to" earlier decision, since current appeal involves validity of claims of reissue patent, which was issue that did not exist at time of decision on validity of original patent claims.

2. Patentability -- Anticipation -- In general (§ 51.201)

Reissue -- In general (§ 58.1)

Patent's reissuance with claims that are not substantially identical to original claim requires evaluation of invention as whole, as currently claimed, in terms of 35 USC 103, and original claims, whether valid or invalid, are not prior art against reissued claims.

3. Patentability -- Aggregation or combination -- In general (§ 51.151)

Federal district court erred by treating each prior art reference as teaching one or more of specific components for use in claimed system, even though such system did not then exist.

Particular patents -- Telephone Switches

Re. 31,144, Feil, Multi-Station Telephone Switching System, holding of invalidity vacated.

Case History and Disposition:

Appeal from District Court for the Southern District of New York, Duffy, J.; 223 USPQ 961 .

Action by Interconnect Planning Corporation, against Thomas E. Feil, Robert O. Carpenter, V Brand, Inc., and Turret Equipment Corp., * for patent infringement and unfair competition, in which defendants counterclaim

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for declaration of patent invalidity. From decision granting defendants' motion for summary judgment, plaintiff appeals. Vacated and remanded.

Attorneys:

Alfred P. Ewert, and Morgan, Finnegan, Pine, Foley & Lee, both of New York, N.Y. (Jerome G. Lee, Robert A. Molan, and Richard J. McGrath, on the brief, and Howard Karasik, and Sherman & Citron, P.C., both of New York, N.Y., of counsel) for appellant.

Lawrence G. Kurland, and Hubbell, Cohen, Steifel & Gross, P.C., both of New York, N.Y. (Lance J. Lieberman, Daniel L. Dolgin, Towne, Dolgin, Sawyer & Horton, Peter P. Stern, Theodore S. Steingut, and Berger, Steingut, Weiner, Fox & Stern, all of New York, N.Y., on the brief) for appellees.

Judge:

Before Davis, Smith, and Newman, Circuit Judges.

Opinion Text

Opinion By:

Newman, Circuit Judge.

Interconnect Planning Corporation (IPC) appeals from the summary judgment of the United States District Court for the Southern District of New York, *Interconnect Planning Corp. v. Feil*, 587 F.Supp. 1495, 223 USPQ 961 (S.D.N.Y. 1984), holding invalid all the claims of IPC's Reissue Patent No. 31,144 entitled "Multi Station Telephone Switching System," invention of Thomas E. Feil, for failure to meet the conditions for patent validity under 35 U.S.C. § 103, and dismissing IPC's count for patent infringement. We hold that invalidity under § 103 has not been proven, as a matter of law. We vacate the summary judgment of invalidity and dismissal of the infringement count, and remand to the district court.

Background

The claims of Reissue Patent No. 31,144 are for certain telephone systems known as "trader

turrets", which are multi-line telephone consoles used by the financial community in trading networks for securities, commodities, currency, and the like. The purpose of these systems is to facilitate concurrent telephone connections for traders requiring multiple sources of price information, conducting multiple transactions, and generally meeting the communication demands of busy, often hectic, financial trading enterprises. Trading rooms may house a hundred or more trader turrets.

Because of the large number of lines and connections required and the specific needs of these communication networks, these systems are complex. A high degree of reliability is required in their operation, because even momentary failures can be extremely costly.

The record shows that the Feil trader turrets rapidly achieved commercial success, displacing other systems then in use. IPC attributes the success of the Feil invention to its novel system "architecture", which enabled ease of operation, high capacity, and improved reliability over the systems then available. IPC's sales of the Feil trader turrets, according to the record, grew from \$320,000 for 20 units in 1974, its first year, to \$27,900,000 for 3500 units in 1983.

Thomas Feil, the inventor, was formerly an officer and part owner of IPC. In 1977 Mr. Feil formed the defendant company V Band Systems, Inc., and in 1980 Mr. Feil left IPC and joined V Band, of which he is president and chief executive officer. Defendants make and sell the trader turrets that are here accused of patent infringement.

On November 21, 1980, IPC filed suit in the Southern District of New York asserting infringement of U.S. Patent No. 3,991,282 (the '282 patent), invention of Thomas Feil. Defendants Feil and V Band raised the defense this patent was invalid in terms of 35 U.S.C. §103. IPC's count for unfair competition was dismissed by the court and is not before us. Various counterclaims were separated and are apparently still pending.

In May of 1981 IPC filed in the U.S. Patent and Trademark Office (the PTO) an application to reissue the '282 patent. IPC cited to the examiner articles by M.E. Ozenberger and W.H. Keith, both of the Bell Telephone Laboratories, on which articles defendants were relying before the district court, and which had not previously been before the examiner. The district court refused to stay the action before it pending completion of the reissue examination, and therefore the reissue examination was suspended by the PTO in accordance with its rules. On defendants' motion for summary judgment, the district court on June 1, 1982 held all claims of the '282 patent invalid for obviousness under 35 U.S.C. § 103. *Interconnect Planning Corp. v. Feil*, 543 F.Supp. 610, 614-19, 215 USPQ 734, 736-41 (S.D.N.Y. 1982).

Following this decision, at IPC's request the PTO resumed examination of the reissue application. The court's decision was provided to and considered by the examiner. A supple

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mental reissue declaration by IPC referred to this decision as a basis for the reissue application. The '282 patent was surrendered, and on February 8, 1983 the PTO granted the reissue patent, RE 31,144, IPC having restricted its claims in various ways and having overcome the newly cited prior art.

Defendants moved for summary judgment of invalidity of the reissue patent, asserting collateral estoppel based on the court's decision on the '282 patent, and also asserting invalidity under 35 U.S.C. § 103. IPC resisted the motion, and the parties' memoranda, affidavits,

depositions, and other documents are of record. For reasons similar to those of the 1982 decision, the motion for summary judgment was granted on June 20, 1984.

That decision, holding all of the reissue claims invalid, was certified and made final under Fed.R. Civ. P. 54(b), with instructions by the court that IPC "attempt to have any appeal . . . heard at the same time and before the same panel" as any appeal from a decision on the same patent by the United States District Court for the District of New Jersey.¹ We agreed. Both appeals are decided this day.

Although both appeals involved similar issues and argument, specific to the New York suit are certain procedural issues, as discussed *infra*.

Collateral Estoppel

Defendants argue that IPC's appeal rights are curtailed on the basis of collateral estoppel. Two separate but related issues of estoppel are raised, both arising out of the district court's 1982 decision on the '282 patent.

A.

Defendants assert first that IPC can not now appeal from or argue those aspects of the 1984 decision on the reissue patent which are "common to" the 1982 decision on the '282 patent, on the ground that those aspects could have been appealed earlier, and that it is too late to do so now. IPC asserts in response that (1) the issues are not the same, (2) a different patent is involved, and (3) the 1982 decision was not final.

Considering the finality issue, for collateral estoppel to arise the prior decision need not have been final in the sense of 28 U.S.C. § 1291 but, in the words of the Restatement, the prior adjudication must have been "sufficiently firm to be accorded conclusive effect". Restatement (Second) of Judgments § 13 (1982). Sufficient firmness, according to the Restatement, requires that the party against whom the estoppel is asserted have had the right, even if not exercised, to challenge on appeal the correctness of the earlier decision. Restatement (Second) of Judgment, § 13 reporter's note comment f (1982). Defendants argue that IPC had three such opportunities: appeal under 28 U.S.C. § 1292(a)(1), which governs appeals from interlocutory orders involving injunctions; appeal under 28 U.S.C. § 1292(c)(2), which governs appeals in patent infringement cases final except for an accounting; and appeal under Fed.R.Civ.P. 54(b), which governs judgment on fewer than all of multiple claims in an action.

None of these situations controls the case before us. 28 U.S.C. § 1292(a)(1) relates to orders involving injunctions, and although defendants argue that IPC's complaint necessarily invokes this section, this does not impart automatic appealability to interlocutory orders that do not involve injunctions. As for 28 U.S.C. § 1292(c)(2), the district court's judgment was not final except for an accounting, in light of the pendency of counterclaims. 9 J. Moore, B. Ward, & J. Lucas, Moore's Federal Practice, ¶ 110.19[4], at 220 (1985). Fed.R. Civ. Proc. 54(b) requires that the court have expressly directed entry of a final judgment, and that "[i]n the absence of such determination and direction, any [decision] which adjudicates fewer than all the claims . . . shall not terminate the action as to any of the claims". See also 6 Moore's Federal Practice ¶ 54.42, at 813.

Neither IPC nor the defendants asked the district court to enter a final judgment on its decision holding the '282 patent invalid, and the court did not do so. Defendants assert, however,

that IPC should now be estopped because it did not move for finality of the ruling nor request that the judgment be certified for interlocutory appeal. An application for certification is by no means certain to be granted and, in this case, IPC's eventual request for certification of the original decision was opposed by defendants and was refused by the court.

The law of collateral estoppel is not intended to penalize a party for declining to try to take a piecemeal appeal. Further, the '282 patent had been placed in reissue, and an appeal on the merits of patent claims for which reissue was being sought would have been a meaningless exercise, as may have been recognized at the time.

[1] We conclude that the district court's 1982 decision on the '282 patent claims, a

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decision not final, not certified, not appealed, and mooted by subsequent events, lacks collateral estoppel effect for the purpose urged by defendants. The issue here on appeal is the validity of the claims of the reissue patent, an issue that did not exist at the time of the decision on validity of the '282 patent claims. There is no estoppel against appellate review of all aspects pertinent to the decision on the reissue claims. 1B Moore's Federal Practice ¶ 0:441 [3.-3], at 737.

B.

IPC asserts that the district court incorrectly invoked collateral estoppel when it analyzed the reissue claims by comparing them with the original claims of the '282 patent, then applying prior art only to the differences between the reissue claims and the original claims. Our predecessor court, the U.S. Court of Claims,² has confronted related situations, wherein estoppel was raised as to unadjudicated claims of a patent whose other claims had been adjudicated in an earlier action. The Court of Claims adopted a pragmatic approach, stating that the first step was to determine whether any new issues were raised as to the nonlitigated claims. In *Westwood Chemical, Inc. v. United States*, 525 F.2d 1367, 1375, 187 USPQ 656 (Ct.Cl. 1975), adopting 186 USPQ 383, 389 (Ct.Cl.Tr.Div. 1975), the court said:

Where obviousness is the basis for the prior invalidity holding, an inquiry into the identity of the validity issue is more properly phrased in terms of the factual inquiries mandated by *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 466-467, S.Ct. 684, 15 L.Ed.2d 545 (1966), as a prerequisite to such a validity determination.

Applying the *Graham* guidelines, the court said:

Thus, the inquiry should be whether the nonlitigated claims present new issues as to the art pertinent to the nonlitigated claims; as to the scope and content of that art; as to the differences between the prior art and the nonlitigated claims; and as to the level of ordinary skill in that art. If none of these inquiries raises any new triable issues, then the obviousness determination in the prior proceeding should be equally applicable to the nonlitigated claims.

Id. See also *Bourne, Inc. v. United States*, 537 F.2d 486, 199 USPQ 256 (Ct. Cl. 1976), adopting 187 USPQ 174 (Ct. Cl. Tr. Div. 1975); *Carter-Wallace, Inc. v. United States*, 496 F.2d 535, 538, 182 USPQ 172, 175 (Ct. Cl. 1974) (in determining the applicability of the estoppel, the first consideration is "whether the issue of invalidity common to each action is

substantially identical.").

The question of substantial identity of reissue claims arose in *Plastic Container Corp. v. Continental Plastics of Oklahoma, Inc.*, 607 F.2d 885, 203 USPQ 27 (10th Cir. 1979), *cert. denied*, 444 U.S. 1018, 204 USPQ 696 (1980), wherein the court determined that the reissue claims were not substantially identical to the original claims, and therefore that collateral estoppel did not apply.

In *Bourns*, responding to plaintiff's argument that according collateral estoppel effect to non-identical adjudicated claims would amount to treating the claims previously held to be invalid as prior art, the court agreed that this would be inappropriate:

A domino approach in which each successively narrower claim is compared with the one before it, not with the prior art, is inappropriate since it improperly gives prior-art effect to the subject matter of an invalid claim. *In re Craig and Street*, Cust. & Pat. App., 411 F.2d 1333, 1335, 162 USPQ 157, 158-159 (1969).

537 F.2d at 493, 187 USPQ at 179.

The district court compared the reissue claims with the '282 claims, and erroneously concluded that reissue claims 1 through 6 were substantially identical to the original claims, and that reissue claims 7 through 9, although not substantially identical, involved some substantially identical "issues".

This erroneous legal conclusion may have compounded the error in the next step, wherein the court compared the differences between the original and the reissue claims with prior art that was pertinent only to those differences, thus effectively giving the original claims prior art effect -- the pitfall against which *Bourns* cautioned:

A claim may be invalid for obviousness under 35 U.S.C. § 103 but still describe a combination not found in the prior art. Moreover, it is well settled that each claim of a patent is entitled to a presumption of validity and is to be treated as a complete and independent invention. 35 U.S.C. § § 282, 288. *Leeds & Catlin v. Victor Talking Machine Co.*, 213 U.S. 301, 319, 29 S.Ct. 495, 53 L.Ed. 805 (1909); *Smith Industries International v. Hughes Tool Co.*, 396 F.2d 735, 736 (5th Cir. 1968).

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[2] *Id.* When a patent has been reissued with claims that are not substantially identical to the original claims, the invention as a whole, as now claimed, must be evaluated in terms of 35 U.S.C. § 103. The original claims, whether valid or invalid, are not prior art against the reissued claims.

The Summary Judgment

The proceeding from which this appeal is taken was styled "summary", in that the court's decision was made on defendants' motion for summary judgment. The earlier decision on the '282 patent was also made on defendants' motion for summary judgment. IPC contends that the matter was inappropriate to summary judgment, in view of the presence of disputed issues of

material fact.

Defendants Feil and V Band argued before the district court, and repeat before us, that no material fact is in dispute, that the questions before the district court and before us in this appeal are purely legal ones, and that the issue was properly dealt with summarily. In its discussion of reissue claims 7 through 9, which claims had no counterpart in the original patent, the district court referred to "claims and issues that have not yet been subjected to a full and fair adjudication", 587 F.Supp. at 1500, 223 USPQ at 965; the court viewed both proceedings as "full" as well as fair, a process not always accommodated by summary proceedings on a documentary record.

Obviousness *vel non* under 35 U.S.C. § 103 is a question of law, whose conclusion requires preliminary determination of several underlying factual issues, as set out in *Graham v. John Deere Co.*, 338 U.S. 1, 148 USPQ 459 (1966). *See also Gardner v. TEC Systems, Inc.* 725 F.2d 1338, 1344-45, 220 USPQ 777, 782-83 (Fed. Cir.) (in banc), *cert. denied*, 105 S.Ct. 116, 225 USPQ 232 (1984). These factual issues relate to the scope and content of the prior art, the differences between the prior art and the claimed invention as a whole, the level of ordinary skill in the art at the time the invention was made, and the so-called "secondary considerations" that reflect the contemporaneous response to the invention.

In reviewing IPC's assertions that there were genuine issues of material fact relating to the *Graham* inquiries, we have reviewed the submissions of the parties. Before the court, according to the record, were all the references cited as prior art; as well as the depositions of Examiner Randall P. Myers of the United States Patent and Trademark Office, engineer John Fitzmaurice of New York Telephone, and inventor/defendant Thomas E. Feil; and various documentary exhibits. Also of record were the affidavits of Alan R. Fitzpatrick, president of American Telecommunications Concepts; IPC's technical experts Dennis Maywald and Herbert Goldwag; Thomas P. Bradbury, vice president and treasurer of IPC; and extensive written submissions and arguments.

Although fact and opinion are intertwined in many of these documents, the factual considerations required by the *Graham* analysis appear to have been adequately presented in the record. The technological structure and operation of the devices of the prior art were not in material dispute,³ although there was strong dispute about the relationship of the teachings of the references to the problems solved by the Feil system, and the weight to be given to evidence of the Feil invention's commercial success.

The district court stated that expert testimony was unnecessary, *Interconnect Planning Corp. v. Feil*, 587 F.Supp. at 1497, 223 USPQ at 963, and held all of the reissue claims invalid. As will be discussed, we think that the district court reached this conclusion by incorrectly applying the law of 35 U.S.C. § 103.

35 U.S.C. § 103

Those charged with determining compliance with 35 U.S.C. § 103 are required to place themselves in the minds of those of ordinary skill in the relevant art at the time the invention was made, to determine whether that which is now plainly at hand would have been obvious at such earlier time.

The invention must be viewed not with the blueprint drawn by the inventor, but in the state of

the art that existed at the time.

The invention must be evaluated not through the eyes of the inventor, who may have been of exceptional skill, but as by one of "ordinary skill." See *Stewart-Warner Corp. v. City of Pontiac, Michigan*, 767 F.2d 1563,

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1570, 226 USPQ 676, 680-81 (Fed. Cir. 1985).

This is not a facile statutory interpretation. The quality of non-obviousness is not easy to measure, particularly when challenged years after the invention was made. That which may be made clear and thus "obvious" to a court, with the invention fully diagrammed and aided, in this case, by a hostile inventor seeking to eliminate his own invention, may have been a breakthrough of substantial dimension when first unveiled.

The judicial application of uniform standards for determining compliance with 35 U.S.C. § 103 is essential, because the technological incentives fostered by the patent system depend on consistent interpretation of the law. To this end, faithful adherence to the patent statute and guiding precedent fosters uniformity in result.

A.

Following examination by the Patent and Trademark Office, a duly issued patent is presumed valid, as is a duly reissued patent. The burden of proving otherwise resides with the person challenging its validity. 35 U.S.C. §282.

This statutory presumption derives in part from recognition of the technological expertise of the patent examiners. A reissue application receives a fresh examination, normally concentrated on those references and reasons that occasioned its filing. The record shows that this reissue application received a supplemental internal review by three examiners because it was involved in litigation.

Although IPC's view is incorrect that the PTO's decision must be given controlling weight, we do agree that the examination procedure and result should be given appropriate consideration and due weight by the court. As stated in *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, 225 USPQ 26, 31 (Fed. Cir. 1985), "[t]he Examiner's decision, on an original or reissue application, is never binding on the court. It is, however, evidence the court must consider in determining whether the party asserting invalidity has met its statutory burden by clear and convincing evidence".

Upon reissue the "burden of proving invalidity was made heavier", as stated in *Fromson, supra*. This burden must be met by the party asserting invalidity. The district court here relied on the identical references that had been before the reissue examiners, and disdaining the need for expert testimony, reached a different conclusion in law. Although we affirm the obligation of the district court to reach an independent conclusion, the reissue patent reaches the court clothed in a statutory presumption of validity, and clear and convincing evidence is required to surmount this presumption. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60, 220 USPQ 763, 770 (Fed. Cir.), *cert. denied*, 105 S.Ct. 95, 224 USPQ 520 (1984).

B.

The court referred to the content of the prior art references in broad terms, occasionally using the title of a reference to explain its pertinence. In this crowded art of telephone systems, as IPC correctly pointed out, it is not enough to show that each of the components used by Feil was known, and had been used in other telephone systems. Feil did not claim to have invented any of the components of his claimed system.

[3] From its discussion of the prior art it appears to us that the court, guided by the defendants, treated each reference as teaching one or more of the specific components for use in the Feil system, although the Feil system did not then exist. Thus the court reconstructed the Feil system, using the blueprint of the Feil claims. As is well established, this is legal error. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 774, 218 USPQ 781, 791 (Fed. Cir. 1983), *cert. denied*, 104 S.Ct. 1284, 224 USPQ 520 (1984).

Illustrative is the court's analysis of reissue claim 1. Pertinent is not only its analysis of the differences between the reissue claim and the prior art, but also the differences between the reissue claim and the original claim. In claim 1, matter enclosed in brackets appeared in the original claim but forms no part of the reissue claim, and matter printed in italics was added by reissue:

1. For a telephone system in which telephone communication is capable of being established for each telephone station of a plurality of telephone stations over a standard telephone line by directly connecting each telephone station to a selected standard telephone line of a plurality of standard telephone lines, each of said plurality of standard telephone lines capable of being directly connected to each of said plurality of telephone stations, an improvement comprising:

a plurality of pairs of contacts, with respective pairs of said contacts being connected with respective ones of said standard telephone lines for allowing said communication;

a plurality of relay coils, with respective ones of said relay coils controlling respective pairs of said contacts to be opened or closed;

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a plurality of sets of *non-locking* pushbutton [switch means] *switches* with each set of pushbutton [switch means] *switches* connected to respective ones of said telephone stations with respective ones of said pushbutton [switch means] *switches* of said sets of pushbutton [switch means] *switches* corresponding to respective ones of said standard telephone lines and being connected with respective ones of said relay coils and being depressed for energizing a selected one of said relay coils for closing a corresponding pair of contacts to allow said telephone communication; [and]

an *electronic holding circuit for each of said relay coils, said holding circuits being operative*

to establish a held state after initial energization of the associated relay coil by momentarily depressing the associated pushbutton switch, and

to maintain said corresponding pair of contacts closed while in the held state;

a *logic circuit for each station connected to said holding circuits to detect conditions for*

releasing the held state;

each of said stations comprising [first light display means] *a set of status lights*, connection means connecting corresponding pushbuttons of said sets of pushbutton [switch means] *switches* in each of said stations and to said [first light display means] *status lights* for energizing said [first light display means] *status lights* in each station to display the status of each of said plurality of standard telephone lines in each of said stations,

said station further comprising [first light display means] *an active line indicator separate from said status lights* connected to said pushbutton [switch means] *switches* for identifying the standard telephone line *of said plurality of standard telephone lines* that the telephone station is using for said telephone communication.

Reissue claim 1 was held invalid on two grounds. The first ground was that it was substantially identical to claim 1 of the '282 patent, and thus invalid on the basis of collateral estoppel. The court in its 1982 decision referred to Carter U.S. Patent No. 3,150,238 and Foulkes U.S. Patent No. 3,757,056 as disclosing "non-locking buttons, relay coils and pairs of contacts" as applied to the original claim 1. In the 1984 decision the court stated that "Claim 1 has not been changed in such a way that alters the above finding of disclosure by prior art." 587 F.Supp. at 1499, 223 USPQ at 964. This treatment of the reissue claim is not supported by the claim content, as will be apparent from the court's further discussion of claim 1.

As the second ground for its holding of invalidity the court analyzed the changes made by reissue. The court identified three areas as *new* to reissue claim 1, and applied five references to these areas as follows: "See Defendants' Exhs. C13, D4-D6 (non-locking buttons); Defendants' Exhs. C4, C7 (holding circuits); Defendants' Exhs. C16, C13 (separate active lines)." *Id.* at 1499, 223 USPQ at 964 (footnotes omitted).

The first set of cited exhibits refers to articles by Keith, "A New Switching System for 'Right of Way' Companies," *Bell Laboratories Record*, Apr. 1968, and Ozenberger, "Voice Communication System for Air Traffic Control," *Bell Laboratories Record*, May 1961, which the court stated taught the use of non-locking pushbuttons. The second set refers to the Carter patent, which the district court said teaches a "Relay Control Circuit" (the title of the Carter patent), and the Foulkes patent which "recites that '[e]ach of these [control] circuits may take any desired and presently known form . . . to perform a recognized control function . . . evaluat[ing] the 'hold' feature' ". *Id.* at 1499 n.6, 223 USPQ at 946 n.6. The third set of exhibits refers to Simon U.S. Patent No. 3,928,732, which the district court described by its title, "Extension and Line Indicating Display System for Key Telephone System," and Keith, which the district court stated "also discloses separate active lines." *Id.* at 1499 n.7, 223 USPQ at 964 n.7.

The court's analysis of the scope of the new material in reissue claim 1 in itself shows the error in the court's conclusion that as a matter of law reissue claim 1 is substantially identical to its parent claim. The claim limitations of the electronic holding circuits for each relay coil, the logic circuit, and separate active line indicator, in combination with the non-locking pushbutton switches connected to the relay coils, were added by reissue. Observing these differences, their relationship to the invention as a whole, and the prior art, we conclude as a matter of law that reissue claim 1 is not substantially identical to the original claim. The 1982 decision, which was directed to the original claims, does not apply to the reissue claims. Collateral estoppel as a basis for the court's holding of invalidity is not supported in law.

Having determined that a reissue claim is not substantially identical to the parent, the parent

claim is of no further moment. As stated in *Wayne-Gossard Corp. v. Moretz Hosiery Mills, Inc.*, 539 F.2d 986, 991, 191 USPQ 543, 546-47 (4th Cir. 1976), "the original claim was at an end, denuded of all potency save as a bench mark of interpretation, at the time of the reissue's infringement."

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The original claim is not prior art against the reissue claim. It is not correct to weigh the reissue claim against the original claim. It is not correct to weigh the changes in the reissue claim against the original claim. It is the reissue claim alone that is to be analyzed in accordance with the *Graham* guidelines, and the differences to be considered are the differences between the reissue claim as a whole and the prior art.

In the court's 1982 analysis of the original claims, to which the court referred in its 1984 decision, the court had identified "six principal features which plaintiff argues are not obvious" and explained why the court concluded that these features are obvious by referring to various prior art references showing various of the features in various contexts. *Interconnect Planning Corp. v. Feil*, 543 F.Supp. at 617, 215 USPQ at 739. As we have observed, it is the emphasis on the obviousness of "features," rather than the claimed telephone system as a whole, that constitutes the flaw in the application of section 103 to the Feil claims. As stated in *In re Shuman*, 361 F.2d 1008, 1012, 150 USPQ 54, 57 (CCPA 1966):

It is impermissible to first ascertain factually what appellants *did* and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants' invention from such prior art.

The court in 1982 summarized its conclusion with respect to these six "features" by observing (1) that although the pairs of contacts and relay coils "is not disclosed in either the Keith Article or the Ozenberger Article", the Foulkes and Carter patents do disclose them; (2) that Keith, Ozenberger, and Foulkes refer to pushbutton switches; (3) that Keith shows a set of display lamps although Ozenberger uses a single lamp, and that Paraskevacos (U.S. Patent No. 3,727,003) and Simon et al. show either a digital display or the incoming line number; (4) that Paraskevacos shows a decoder and that "the diode matrix was no mystery to one engineer" (Thomas Fitzmaurice, of Bell Labs, who testified that he readily understood the Feil system after he was shown it); (5) that Keith shows which lines are active; and (6) that the asserted unique master station hook up with blocking means is shown in Ozenberger and a Verdon patent (U.S. Patent No. 3,819,871). *Interconnect Planning Corp. v. Feil*, 543 F.Supp. at 617-19, 215 USPQ at 739-40.

In its 1984 decision the court added the additional citations of references pertinent to the changes in the reissue claims, as discussed above. As in its citation of references against the various features of the original claims, the court selected from each reference a feature or features that also appeared in the reissue claims. No reference, however, suggested the overall arrangement, the "architecture", of the Feil system.

IPC presented affidavit testimony explaining the references in the context of the state of the telephone systems art at the time, none of which testimony was controverted other than by attorney argument. The most advanced multi-line devices at the time the invention was made, according to this record, used the then state-of-the-art crossbar switching equipment, and

electrical or mechanical interconnections or interlocks. The two Bell Labs publications of Keith and Ozenberger, on which defendants and the district court placed substantial emphasis, used crossbar switching. Feil did not.

Mr. Feil's affidavit filed with the district court states "The Ozenberger and Keith articles disclose what I thought I invented in 1974". Mr. Feil made no reference to the crossbar switches required by these references, and offered no discussion of either differences or similarities between his system and those of these references.

The Carter patent used relay switches in the telephone switching system it describes. Carter, of Bell Laboratories, taught the use of quick-release control relays in combination with slow-release work relays, to achieve the specific purposes desired by Carter. Carter also required use of a "locking chain" rather than independently operating relays, and a more complex communication path as compared with Feil's direct connections. Feil established multiple direct connections in a system where theretofore it was believed, according to the record, that crossbar switches would be required.

The Feil system eliminated both crossbar switches and mechanical interlocks or mechanically locking pushbuttons, and instead used relays, a well-known type of switch. But Feil avoided the need (of Carter) to establish potentially large numbers of contacts and operates a concomitantly large number of relays in series in order to connect stations within the system. As IPC's uncontroverted testimony shows, Feil avoided interconnections and interlocks, both of which, according to the Maywald affidavit, had previously been considered necessary to lock out faults. The Maywald affidavit stated that Carter's approach would be "impossible and impractical" in the trader turret application because "[t]o try and accurately control the release times of different relays over a long period of time would be virtually impossible considering the wear and deterioration of components" in a "trader turret network involving some 20,000 or more relays". Maywald's explanation of the

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technical operation of the references is uncontradicted, although defendants take issue in attorney argument with Maywald's conclusions.

The Foulkes patent, on which the district court also relies, described a "bipolar multiplexing circuit" based on a "contact tree" relay switching arrangement. Foulkes taught a telephone system that Maywald avers, without contradiction, "could not be realistically expanded into large systems like trader turrets". The district court did not explain how the Foulkes or other systems of different circuitry made obvious the different system of Feil's claims.

The Keith and Ozenberger systems, as previously discussed, are different systems from that of Feil. Like the systems of the other references, they contain some elements in common with that of Feil. the Ozenberger system, based on crossbar switches, was designed for air traffic control. The Keith system is described as tailored to the specific needs of "right-of-way" companies, and is a cordless system limited to up to eight consoles of up to a hundred lines. As Keith says, "[a] system of crossbar switches is the heart of the switching system". Neither Keith nor Ozenberger suggests that the crossbars be replaced with relays and that the other changes be made to produce the admittedly different Feil system.

The novelty of the Feil system is not controverted by the defendants. Its value in trader turret

systems has received the ultimate recognition, market success and imitation.

35 U.S.C. § 103 requires that obviousness be determined with respect to the invention as a whole. *See, e.g., Jones v. Hardy*, 727 F.2d 1524, 1528, 220 USPQ 1021, 1024 (Fed. Cir. 1984); *W.L. Gore & Assocs, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 172 (1984); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537, 218 USPQ 871, 877 (Fed. Cir. 1983). This is essential for combination inventions, for generally all combinations are of known elements. *Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983), *cert. denied*, 104 S.Ct. 709, 224 USPQ 520 (1984).

When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 & n.14, 221 USPQ 929, 933 & n.14 (Fed. Cir. 1984). There must be "something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination". *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984).

Critical to the analysis is an understanding of the particular results achieved by the new combination. The claims here at issue are directed to a combination of known components of telephone systems in an admittedly new way to achieve a new total system. Neither the district court in its opinion, nor the defendants, identified any suggestion in the prior art that the components be combined as they were by Feil or that such combination could achieve the advantages of the Feil system.

Not only must the claimed invention as a whole be evaluated, but so also must the references as a whole, so that their teachings are applied in the context of their significance to a technician at the time -- a technician without our knowledge of the solution. The defendants propounded and the district court appears to have followed an analytical method that well illustrates the "mosaic" analogy discussed in *W.L. Gore & Assocs.*, 721 F.2d at 1552, 220 USPQ at 312, where this court said:

[T]he claims were used as a frame, and individual naked parts of separate prior art references were employed as a mosaic to recreate a facsimile of the claimed invention.

Defendants refer to the decision of the Supreme Court in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449 (1976). As the Court there held, Sakraida's combination of old elements to wash barn floors with flowing water did not produce a new or different function, and affirmed the district court's holding that " 'all of the elements of [the combination] are old . . . and the combination of them . . . being neither new nor meeting the test of non-obviousness.' " *Id.* at 274, 189 USPQ at 450. In the Feil invention the combination was admittedly new, and it produced a new system having theretofore unavailable attributes.

Recognizing the difficulty of casting one's mind back to the state of technology at the time the invention was made, courts have long recognized the usefulness of evidence of the contemporaneous attitude toward the asserted invention. A retrospective view of the invention is best gleaned from those who were there at the time. Mr. Feil, the inventor impugning his own invention, now avers that he did no more than did the prior art, specifically the Keith and Ozenberger articles. Mr. Feil's disavowal of his invention is staunch, although he less modestly

commented in 1977, before he left IPC, on the reaction of Bell Labs' engineer at that earlier time:

He [Fitzmaurice] showed too much enthusiasm. I mean, he was really excited by the

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thing. Like this is incredible. You guys are geniuses.

You're 50 miles ahead of Bell Labs. (App. Vol. VI, F357).

You know what he said. He said You're 50 miles ahead of Bell Lab? He said "miles", not years, he made it in miles. You're 50' miles ahead of the Bell Labs. (App. Vol. VI, F355).

Mr. Elia of the Republic Bank, one of IPC's customers, attested:

Upon viewing the equipment, the AT&T people indicated that it was unbelievable. They did not think it could be done. They were surprised that it was done. (App. Vol. VI, F360).

Although the district court remarked in its 1982 decision that evidence of commercial success "cannot be afforded any weight" "in light of my finding of obviousness", 543 F.2d at 619, 215 USPQ at 741, such evidence when present must be considered and afforded appropriate weight. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575, 222 USPQ 744, 746 (Fed. Cir. 1984), *cert. denied*, 105 S.Ct. 2138 (1985); *Jones v. Hardy*, 727 F.2d at 1530, 220 USPQ at 1026; *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1575, 220 USPQ 97, 105 (Fed. Cir. 1983); *Stratoflex, Inc.*, 713 F.2d at 1538-39, 218 USPQ at 879; *In re Sernaker*, 702 F.2d 989, 996, 217 USPQ 1, 7 (Fed. Cir. 1983); *In re Mageli*, 470 F.2d 1380, 1383, 176 USPQ 305, 307 (CCPA 1973). IPC offered affidavit and deposition evidence, by two experts in telephone systems and by a Bell system engineer knowledgeable in the field of trader turrets. Their uncontroverted testimony was to the effect that the Feil system was perceived at the time as an exceptional technological achievement.

The requirement that "secondary considerations" be considered in determinations under section 103 aids in evaluating the state of the art at the time the invention was made. *In re Piasecki*, 745 F.2d 1468, 1475, 223 USPQ 785, 790 (Fed. Cir. 1984). It is not pertinent that the invention was easily understood after it was made -- a factor that appears to have been considered significant by the district court, *see* 543 F.Supp. at 619, 215 USPQ at 741 -- but whether it would have been obvious to make the invention at the time. Giving due weight to the market success and contemporaneous reaction to the Feil trader turret system, the record does not contain clear and convincing evidence that the Feil invention of the reissue claims would have been obvious to one of ordinary skill in this art at the time the invention was made.

Reissue claims 2-9 are either dependent on reissue claim 1, include similar limitations, or include additional limitations. Although each claim has been considered separately, they need not here be treated in redundant detail. For each claim we are compelled to the conclusion that the burden of proving invalidity by clear and convincing evidence has not been met.

The summary judgment of invalidity of Reissue Patent No. 31,144, in terms of 35 U.S.C. § 103, is vacated, as is the dismissal of the infringement claim. The case is remanded to the district court for further proceedings consistent herewith.